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Presidential Documents

Title 3—

The President

Proclamation 9492 of September 14, 2016

To Modify Duty-Free Treatment Under the Generalized System of Preferences

By the President of the United States of America

A Proclamation

1. Section 502 of the Trade Act of 1974, as amended (the "1974 Act") (19 U.S.C. 2462), authorizes the President to designate countries as beneficiary developing countries, and to designate any beneficiary developing country as a least-developed beneficiary developing country, for purposes of the Generalized System of Preferences (GSP) program. Section 502(f)(1)(A) of the 1974 Act (19 U.S.C. 2462(f)(1)(A)) requires the President to notify the Congress before designating any country as a beneficiary developing country. Section 502(f)(1)(B) of the 1974 Act (19 U.S.C. 2462(f)(1)(B)) requires the President to notify the Congress at least 60 days before designating any country as a least-developed beneficiary developing country.

2. Pursuant to section 502(a)(1) of the 1974 Act, and taking into account the factors set forth in section 502(c) (19 U.S.C. 2462(c)), I have determined that the suspension pursuant to Proclamation 5955 of April 13, 1989, of preferential treatment for Burma as a beneficiary developing country under the GSP program should be ended, and I will so notify the Congress.

3. Pursuant to section 502(a)(2) of the 1974 Act, and having considered the factors set forth in sections 501 (19 U.S.C. 2461) and 502(c), I have also determined that Burma should be designated as a least-developed beneficiary developing country for purposes of the GSP program, and I will so notify the Congress.

4. Section 604 of the 1974 Act (19 U.S.C. 2483), as amended, authorizes the President to embody in the Harmonized Tariff Schedule (HTS) of the United States the substance of the relevant provisions of that Act, and of other Acts affecting import treatment, and actions thereunder, including removal, modification, continuance, or imposition of any rate of duty or other import restriction.

NOW, THEREFORE, I, Barack Obama, President of the United States of America, acting under the authority vested in me by the Constitution and the laws of the United States of America, including title V and section 604 of the 1974 Act (19 U.S.C. 2461–67, 2483), do proclaim that:

(1) In order to reflect in the HTS the restoration of preferential treatment for Burma as a beneficiary developing country under the GSP program, general note 4(a) is modified by adding in alphabetical order "Burma" to the list entitled "Independent Countries" and to the list entitled "Member Countries of the Association of South East Asian Nations (ASEAN)."

(2) In order to reflect in the HTS the designation of Burma as a least-developed beneficiary developing country under the GSP program, general note 4(b)(i) is modified by adding in alphabetical order "Burma."

(3) The modifications to the HTS made by paragraphs (1) and (2) of this proclamation shall be effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after the date that is 60 days after the date of this proclamation.

(4) Any provisions of previous proclamations and Executive Orders that are inconsistent with the actions taken in this proclamation are superseded to the extent of such inconsistency.

IN WITNESS WHEREOF, I have hereunto set my hand this fourteenth day of September, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and forty-first.

[FR Doc. 2016–22507
Filed 9–15–16; 8:45 am]
Billing code 3295–F6–P

Presidential Documents

Executive Order 13739 September 14, 2016

Termination of Emergency With Respect to the Situation in or in Relation to Côte d'Ivoire

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*), the National Emergencies Act (50 U.S.C. 1601 *et seq.*) (NEA), section 5 of the United Nations Participation Act, as amended (22 U.S.C. 287c), and section 301 of title 3, United States Code,

I, BARACK OBAMA, President of the United States of America, find that the situation that gave rise to the declaration of a national emergency in Executive Order 13396 of February 7, 2006, with respect to the situation in or in relation to Côte d'Ivoire, including the massacre of large numbers of civilians, widespread human rights abuses, significant political violence and unrest, and attacks against international peacekeeping forces leading to fatalities, has been significantly altered by the progress achieved in the stabilization of Côte d'Ivoire, including the successful conduct of the October 2015 presidential election, progress on the management of arms and related materiel, and the combating of illicit trafficking of natural resources. Accordingly, and in view of the removal of multilateral sanctions by the United Nations Security Council in Resolution 2283, I hereby terminate the national emergency declared in Executive Order 13396, revoke that order, and further order:

Section 1. Pursuant to section 202(a) of the NEA (50 U.S.C. 1622(a)), termination of the national emergency declared in Executive Order 13396 shall not affect any action taken or proceeding pending not finally concluded or determined as of the date that this order is effective, any action or proceeding based on any act committed prior to such date, or any rights or duties that matured or penalties that were incurred prior to such date.

Sec. 2. This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Sec. 3. This order is effective at 8:00 a.m. eastern daylight time on September 14, 2016.

THE WHITE HOUSE,
September 14, 2016.

[FR Doc. 2016–22454
Filed 9–15–16; 8:45 am]
Billing code 3295–F6–P

Rules and Regulations

Federal Register
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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 56

[Doc. No. AMS–LPS–15–0044]

Amendment to the Definition of "Condition" and Prerequisite Requirement for Shell Eggs Eligible for Grading and Certification Stated in the Regulations Governing the Voluntary Grading of Shell Eggs

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: The Agricultural Marketing Service (AMS) will amend the Regulations Governing the Voluntary Grading of Shell Eggs to clarify the definition of "condition" and revise the prerequisite requirement for shell eggs eligible for voluntary USDA grading and certification.

DATES: This final rule is effective September 16, 2016.

FOR FURTHER INFORMATION CONTACT: David Bowden, Chief, Standardization Branch, Quality Assessment Division; Livestock, Poultry, and Seed Program, Agricultural Marketing Service, U.S. Department of Agriculture; 1400 Independence Avenue SW.; Room 3932–S, STOP 0258; Washington, DC 20250, by facsimile to (202) 690–2746; or via email to *David.Bowden@ams.usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 203(c) of the Agricultural Marketing Act of 1946 (AMA) (7 U.S.C. 1621–1627) directs and authorizes the Secretary of Agriculture "to develop and improve standards of quality, condition, quantity, grade and packaging, and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices." The U.S. Department of Agriculture (USDA) is committed to carrying out this authority in a manner that facilitates the marketing of agricultural products while maintaining the integrity of the USDA grademark. Shell egg grading is a voluntary program provided under AMA and offered on a fee-for-service basis. It is designed to assist in the orderly marketing of shell eggs by providing the official certification of egg quality, size, condition, and other factors.

This amendment is in accordance with recommendations stated in the 2012 Audit Report, *USDA Controls Over Shell Egg Inspections,* issued by the USDA Office of Inspector General (OIG). In that report, OIG stated the regulatory definition of "condition" for shell eggs was confusing as it relates to quality and food safety. OIG also stated the integrity of the USDA grademark for quality was not adequately protected from adulterated shell eggs.

AMS will revise the definition of "condition" to remove any food safety implications resulting from the use of the term "wholesomeness" and clarify that AMS' role in grading and certification of shell eggs is solely for a quality determination. The revised definition will remove the term "wholesomeness" and state that "condition" is a characteristic detected by a sensory examination. The presence of microorganisms, specifically Salmonella Enteritidis (SE) or other pathogens, in the content of an egg cannot be detected during such an examination. The Food and Drug Administration (FDA) and the USDA Food Safety and Inspection Service not AMS, maintain jurisdiction for food safety related issues associated with shell eggs.

AMS will also revise the prerequisite requirement of shell eggs eligible for USDA grading and certification. The revision will prohibit the use of SE-adulterated or recalled shell eggs from being presented to USDA for grading and certification. This action protects the integrity of the USDA grademark for quality and is consistent with current AMS policy implemented subsequent to the referenced 2012 OIG audit.

Comments

A proposed rule to amend the definition of "condition" and prerequisite requirements for shell eggs eligible for grading and certification stated in the Regulations Governing the Voluntary Grading of Shell Eggs was published in the **Federal Register** (81 FR 23188) on April 20, 2016. Comments on the proposed rule were solicited from interested parties until June 20, 2016. One comment was received from a representative of an egg farmer's organization. The comment received was in support of amending the definition of "condition" and the prerequisite requirements for shell eggs eligible for grading and certification. No changes were made to the proposed rule based on the comment received.

Executive Order 12866, 13175 and 13563

USDA is issuing this final rule in conformance with Executive Orders 12866, 13175 and 13563. This rule has been reviewed under Executive Orders 12866, 13175 and 13563. The rule has determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget. The rule does not promote policies with tribal implications. Consistent with the requirements of Executive Order 13563, the public has had the opportunity to review and comment on the rule; and, the rule also incorporates existing AMS policy on shell eggs eligible for USDA grading and certification.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–602, AMS has performed an initial regulatory flexibility analysis regarding economic effects of this final rule on small entities.

AMS is amending the Regulations Governing the Voluntary Grading of Shell Eggs, 7 CFR part 56, to revise the definition of the term "condition" to clarify that it relates solely to a quality determination and not food safety. The current regulation definition for "condition" includes the term "wholesomeness" which denotes a food safety connotation. AMS' role in grading and certification of shell eggs is for a quality determination only. By removing any food safety related terms from the current definition of "condition," AMS will remove confusion or misunderstanding over use of the term.

Since this change is a technical correction and editorial in nature, and will not result in a change to the way service is provided to our customers, AMS has determined it will not have a financial impact on small entities that utilize our services.

AMS will also revise the prerequisite requirement of shell eggs eligible for USDA grading and certification. The revision will prohibit the use of SE-adulterated shell eggs or recalled shell eggs from being presented to USDA for grading and certification.

The FDA prohibits the use of SE-adulterated shell eggs from being sold to consumers. When shell eggs are suspected of being adulterated with SE, the packing facility is obligated to test the shell eggs to assure only safe product is distributed to consumers. If shell eggs are found to be adulterated with SE, the FDA will issue a request to the packing facility to voluntarily recall the product, or will exercise its mandatory recall authority to return the product to the origin facility. The product must either be destroyed or reconditioned under FDA supervision.

Since SE-adulterated shell eggs or shell eggs that have been recalled are no longer eligible for distribution to consumers, but are either destroyed or reconditioned under the direction of the FDA, changing the AMS regulation will not have an impact on small entities since those shell eggs are deemed unfit for human consumption.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. When this final rule is adopted: (1) All State and local laws and regulations that are inconsistent with the rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), OMB has approved the information collection and recordkeeping requirements included in this final rule, and there are no new requirements. The assigned OMB control number is 0581–0128, as approved on July 8, 2014.

AMS is committed to compliance with the Government Paperwork Elimination Act, which requires government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible.

E-Government Act

AMS is committed to complying with the E-Government Act of 2002 to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to government information and services, and for other purposes.

List of Subjects in 7 CFR Part 56

Agriculture, Eggs and egg products, Food grades and standards, Food labeling, Food packaging, Reporting and recordkeeping requirements, Voluntary standards.

For the reasons set forth in the preamble, 7 CFR part 56 is amended as follows:

PART 56—VOLUNTARY GRADING OF SHELL EGGS

■ 1. The authority citation for 7 CFR part 56 continues to read as follows:

Authority: 7 U.S.C. 1621 *et seq.*

■ 2. Amend § 56.1 by revising the definition of *Condition* to read as follows:

§ 56.1 Meaning of words and terms defined.

* * * * *

Condition means any characteristic detected by sensory examination (visual, touch, or odor), including the state of preservation, cleanliness, soundness, or fitness for human food that affects the marketing of the product.

* * * * *

■ 3. Amend § 56.40 by revising paragraphs (c)(2) and (3) and adding paragraphs (c)(4) and (5) to read as follows:

§ 56.40 Grading requirements of shell eggs identified with grademarks.

* * * * *

(c) * * *

(2) Not possess any undesirable odors or flavors;

(3) Not have previously been shipped for retail sale;

(4) Not originate from a layer house environment determined positive for the presence of Salmonella Enteritidis (SE), unless the eggs from the layer house have been sampled and have tested negative for the presence of SE in the eggs; and

(5) Not originate from eggs testing positive for SE, or not have been subject to a product recall.

Dated: September 12, 2016.

Elanor Starmer,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2016–22246 Filed 9–15–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 930

[Doc. No. AMS–FV–15–0047; FV15–930–2 FR]

Tart Cherries Grown in the States of Michigan, et al.; Revision of Optimum Supply Requirements and Establishment of Inventory Release Procedures

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule implements recommendations from the Cherry Industry Administrative Board (Board) to add inventory release procedures and revise optimum supply provisions under the marketing order for tart cherries grown in the States of Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin (order). The Board locally administers the order and is comprised of growers and handlers operating within the area of production. This final rule establishes procedures for releasing inventory from reserves and increases the maximum carry-out volume available when calculating optimum supply from 20 million pounds to 100 million pounds. These changes provide clear procedures should an inventory release be necessary and provides more flexibility when calculating optimum supply.

DATES: Effective September 19, 2016.

FOR FURTHER INFORMATION CONTACT: Jennie M. Varela, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 291–8614, or Email: *Jennie.Varela@ams.usda.gov* or *Christian.Nissen@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–

2491, Fax: (202) 720–8938, or Email: *Richard.Lower@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This final rule is issued under Marketing Order No. 930, as amended (7 CFR part 930), regulating the handling of tart cherries grown in the States of Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the "Act."

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 12866, 13563, and 13175.

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This final rule adds inventory release procedures and revises the optimum supply and exemption provisions under the order. This rule establishes procedures for releasing inventory from reserves and increases the maximum carry-out volume available when calculating optimum supply from 20 million pounds to 100 million pounds. These changes provide clear procedures should an inventory release be necessary and provides more flexibility when calculating optimum supply. The Board voted to recommend these changes to the Secretary at its meeting on June 25, 2015.

Section 930.50 prescribes procedures for calculating an optimum supply based on sales history to determine free and restricted percentages under volume regulation. As part of the process, the Board is required to determine the volume of fruit they anticipate would be necessary to have on hand at the end of the crop year. The order refers to this volume as carry-out inventory. This section currently specifies, in part, that the Board can consider a carry-out inventory of up to 20 million pounds, or another amount with the approval of the Secretary. This rule amends Section 930.151 to increase the maximum carry-out volume available when calculating optimum supply from 20 million pounds to 100 million pounds.

Section 930.54 of the order governs the use or disposition of inventory reserve cherries. Under this authority, the Board can recommend to the Secretary that a portion or all of inventory reserve cherries be released if there is not sufficient fruit on the market to meet commercial demand. Sections 930.55 and 930.57 outline the provisions and requirements of the primary and secondary reserves, respectively. Further, no cherries in the secondary reserve may be released until all cherries in the primary reserve have been released. This rule creates section 930.154 to establish procedures for releasing inventory from reserves.

When volume regulation is in place, the restricted portion of the crop is either held in reserve by handlers or can be sold for exempt uses as authorized in the rules and regulations of the order. Reserves can be held over multiple crop years and are released when there is a shortfall in supply. While the Board maintains record of the volume in reserve, handlers maintain ownership of the reserve fruit.

All inventory reserves were released to meet demand following a crop disaster in 2012. The following year, the industry was still recovering and the Board did not recommend a volume regulation. When the Board recommended a volume regulation for the 2014–15 season to the Secretary, and cherries were again being added to the reserve, the Board established a committee to review the procedures for releasing restricted inventory from reserves. The committee recommended to the Board that the procedures as previously developed by the Board be maintained, and that any release should first come from inventory currently in the primary reserve and then from any cherries designated for reserve from the current season if necessary.

Under these procedures, once the additional volume needed for release is established, the release should be apportioned among handlers based on each handler's prior three-year average of volume handled as a percentage of the industry's three-year average. For example, if a handler handled five percent of the previous three years' production, and the Board recommended a release of 20 million pounds, that handler would be authorized to release one million pounds of established reserves (.05 X 20 million). If a handler receives a release larger than what they have in the primary reserve, the excess amount would be reapportioned to those handlers with remaining primary reserve. If the handler in the scenario above had only 750,000 pounds in the primary reserve, the remaining 250,000 pounds would be reallocated to those handlers who still have inventory in the primary reserve.

The committee that reviewed the procedures for releasing restricted inventory from the reserves recognized that inventory reserves can be accumulated over a period of years. Therefore, the committee agreed releases should be based on the average amount handled during the three previous crop years, rather than using a year-to-year basis. The existing release procedures were crafted by the Board through a series of actions in past years and meetings. However, the procedures were not codified in the rules and regulations under the order. This rule adds the inventory release procedures to the regulations.

This recommendation was also thought to be the most equitable way to conduct releases. One Board member believed the releases should come from the current year's reserves prior to releasing from existing reserves, and did not support the recommendation. However, the Board recognized that during the crop year, complete information on reserves and shipment data would not be available. Thus, the Board recommended codifying inventory release procedures as recommended by the committee. The Board supported the recommendation by a vote of 17–1. This rule adds a new Section 930.154 to the regulations to establish procedures for releasing inventory from reserves.

In addition to reviewing inventory release procedures, the Board discussed changes to some of its practices regarding calculation of optimum supply. Optimum supply is defined as the average free sales of the prior three years plus desirable carry-out inventory. Desirable carry-out is the amount of fruit needed by the industry to be carried into the succeeding crop year to meet marketing demand until the new crop is available. Desirable carry-out is set each year by the Board after considering market circumstances and needs. Section 930.50(a) currently specifies that desirable carry-out can range from 0 to a maximum of 20 million pounds, but also authorizes the Board to establish an alternative carry-out figure with the approval of the Secretary.

Since the promulgation of the order, the industry has seen new products and new segments emerge, such as dried tart cherries. As a result, at the end of a season there are multiple product lines that need to be supplied with tart cherries before the next harvest, which has impacted desirable carry-out. Desirable carry-out is the amount of fruit needed by the industry to be carried into the succeeding crop year to meet marketing demand until the new crop is available.

In 2014, the Board used its authority to recommend to the Secretary a carry-out volume above the order-prescribed 20 million pound maximum for the 2014–2015 crop year. At that time, the Board estimated it was necessary to have 50 million pounds available at the end of the crop year to fulfill the needs of the industry. In discussing volume regulation for the 2015–2016 crop year, the Board agreed an increased carry-out was again necessary and recommended to the Secretary a 55 million pound carry-out when calculating the optimum supply.

In order to facilitate future carry-out needs without engaging in annual rulemaking, the Board recommended permanently increasing the maximum carry-out to 100 million pounds. Some members considered the 100 million pound upper limit to be too high, and voted against the recommendation. However, this action only increases the available range for the carry-out value from 0 to 20 million pounds to 0 to 100 million. This change will provide the Board with additional flexibility when considering the carry-out, but in itself does not establish a carry-out amount. The Board will still discuss and recommend a desirable carry-out value that represents current industry needs each crop year. Consequently, the Board supported the recommendation by a vote of 12–5. This rule amends section 930.151 of the regulations to increase the maximum carry-out volume possible when calculating optimum supply from 20 million pounds to 100 million pounds.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 600 producers of tart cherries in the regulated area and approximately 40 handlers of tart cherries who are subject to regulation under the order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts of less than $750,000 and small agricultural service firms have been defined as those having annual receipts of less than $7,500,000 (13 CFR 121.201).

According to the National Agricultural Statistics Service and Board data, the average annual grower price for tart cherries during the 2014–15 crop year was $0.35 per pound, and total utilization was around 300 million pounds. Therefore, average receipts for tart cherry producers were around $175,800, well below the SBA threshold for small producers. In 2014, The Food Institute estimated an f.o.b. price of $0.96 per pound for frozen tart cherries, which make up the majority of processed tart cherries. Using this data, average annual handler receipts were about $6.9 million, which is also below the SBA threshold for small agricultural service firms. Assuming a normal distribution, the majority of producers and handlers of tart cherries may be classified as small entities.

This final rule creates § 930.154 of the rules and regulations, establishing procedures for release of inventory reserves. This final rule also revises § 930.151 to allow the Board to consider a carry-out of up to 100 million pounds when calculating optimum supply. These changes are intended to provide clear direction in the event an inventory release becomes necessary and allow the Board to be more responsive to tart cherry market demand. The authority for these actions is provided in §§ 930.50 and 930.54 of the order.

It is not anticipated that this action will impose additional costs on handlers or growers, regardless of size. The implemented changes are administrative in nature and intended to align the provisions of the order with current industry practices. The addition of rules and regulations regarding inventory releases is a codification of administrative procedures the Board has had in place for many years. The expanded carry-out upper limit will allow the Board additional flexibility in meeting market needs without additional rulemaking.

The benefits of this rule are not expected to be disproportionately greater or less for small handlers or producers than for larger entities.

The Board discussed alternatives to these changes to the order, including releasing reserves from the current crop year or releasing cherries in the order in which the fruit was put into reserve. A committee was established to review the reserve procedures, and it proposed using a three-year average percentage for each handler and releasing the previous crop years' reserves. The Board agreed that the committee's recommendation would be the most equitable solution. Regarding the carry-out limit, the Board considered not recommending a permanent change. However, the Board anticipates needing more than 20 million pounds of carry-out for the foreseeable future. A member suggested changing the motion to 80 million pounds, but that suggestion did not receive support. Thus, the suggested alternatives were rejected.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0177, (Tart Cherries Grown in the States of Michigan, New York, Pennsylvania, Oregon, Utah, Washington, and Wisconsin). No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

Accordingly, this action will not impose any additional reporting or recordkeeping requirements on either small or large tart cherry handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

As noted in the initial regulatory flexibility analysis, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this final rule.

AMS is committed to complying with the E-Government Act to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

The Board's meeting was widely publicized throughout the tart cherry industry and all interested persons were invited to attend and participate in Board deliberations on all issues. Like all Board meetings, the June 25, 2015, meeting was a public meeting and all entities, both large and small, were able to express views on these issues.

A proposed rule concerning this action was published in the **Federal Register** on June 15, 2016 (81 FR 38975). Copies of the rule were mailed or sent via facsimile to all Board members and tart cherry handlers. Finally, the rule was made available through the internet by USDA and the Office of the Federal Register. A 30-day comment period ending July 15, 2016, was provided to allow interested persons to respond to the proposal.

One comment was received during the comment period in response to the proposal. The commenter is an individual who supports the proposed action. The commenter described the proposed changes as positive for the industry. Accordingly, no changes will be made to the rule as proposed, based on the comment received.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant matter presented, including the information and recommendation submitted by the Board and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

It is further found that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** (5 U.S.C. 553) because handlers are already putting cherries into reserve. This action also needs to be in place before the Board meets in September to discuss establishing volume control, including determining an appropriate carry-out figure. Further, handlers are aware of this rule, which was recommended at a public meeting. Also, a 30-day comment period was provided for in the proposed rule.

List of Subjects in 7 CFR Part 930

Marketing agreements, Reporting and recordkeeping requirements, Tart cherries.

For the reasons set forth in the preamble, 7 CFR part 930 is amended as follows:

PART 930—TART CHERRIES GROWN IN THE STATES OF MICHIGAN, NEW YORK, PENNSYLVANIA, OREGON, UTAH, WASHINGTON, AND WISCONSIN

■ 1. The authority citation for 7 CFR part 930 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. In § 930.151:

■ a. Designate the current paragraph as paragraph (a); and

■ b. Add a new paragraph (b) to read as follows:

§ 930.151 Desirable carry-out inventory.

(a) * * *

(b) Beginning with the crop year starting July 1, 2016, for the purposes of determining an optimum supply volume, the Board may recommend a desirable carry-out inventory not to exceed 100 million pounds.

■ 3. Section 930.154 is added to read as follows:

§ 930.154 Release of inventory reserve cherries.

(a) As provided in § 930.54, the Board may recommend a release of a portion or all of the primary and/or secondary reserve cherries. The total available reserves will be determined at the beginning of the crop year. The primary reserve as defined in §§ 930.55 and 930.150 must be depleted before the secondary reserve can be released. If a release is recommended, the recommended volume shall be apportioned to handlers on the basis of each handler's proportion of the total volume handled in the preceding three crop years.

(b) If a handler has less volume in reserve than is apportioned, the excess volume shall be reapportioned to those who still have volume in reserve until the total release is complete.

Dated: September 12, 2016.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2016–22258 Filed 9–15–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 983

[Docket No. AMS–SC–16–0076 SC16–983–2 IR]

Pistachios Grown in California, Arizona, and New Mexico; Decreased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: This rule implements a recommendation from the Administrative Committee for Pistachios (Committee) for a decrease in the assessment rate established for the 2016–17 and subsequent production years from $0.0035 to $0.0010 per pound of assessed weight pistachios handled under the marketing order (order). The Committee locally administers the order and is comprised of producers and handlers of pistachios operating within the area of production. Assessments upon pistachio handlers are used by the Committee to fund reasonable and necessary expenses of the program. The production year begins September 1 and ends August 31. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Effective September 19, 2016; Comments received by November 15, 2016 will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or Internet: *http://www.regulations.gov.* Comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov.* All comments submitted in response to this rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting comments will be made public on the Internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Peter R. Sommers, Marketing Specialist, or Jeffrey Smutny, Regional Director, California Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 487–5901, Fax: (559) 487–5906, or Email: *PeterR.Sommers@ams.usda.gov* or *Jeffrey.Smutny@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Richard.Lower@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement and Order No. 983, both as amended (7 CFR part 983), regulating the handling of pistachios grown in California, Arizona, and New Mexico, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the "Act."

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 12866, 13563, and 13175.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the marketing order now in effect, California, Arizona, and New Mexico pistachio handlers are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the assessment rate as issued herein will be applicable to all assessable pistachios beginning September 1, 2016, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule decreases the assessment rate for the 2016–17 and subsequent production years from $0.0035 to $0.0010 per pound of assessed weight pistachios.

The California, Arizona, and New Mexico pistachio order provides authority for the Committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the Committee are producers and handlers of California, Arizona, and New Mexico pistachios. They are familiar with the Committee's needs and with the costs for goods and services in their local area and are thus in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2015–16 and subsequent production years, the Committee recommended and USDA approved an assessment rate that would continue in effect from production year to production year unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other information available to USDA.

The Committee met on July 12, 2016, and unanimously recommended 2016–17 expenditures of $922,500, and an assessment rate of $0.0010 per pound of assessed weight pistachios. In comparison, last year's budgeted expenditures were $1,056,402, and the assessment rate was $0.0035 per pound of pistachios. The assessment rate of $0.0010 is $0.0025 lower than the rate currently in effect.

The major expenditures recommended by the Committee for the 2016–17 production year include $333,000 for salaries and benefits, $250,000 for research, and $19,500 for general and administrative expenses. Budgeted expenses for these items in the 2015–16 production year were $316,500, $560,000, and $19,500, respectively.

The assessment rate recommended by the Committee was derived by dividing anticipated expenses by expected shipments of California, Arizona, and New Mexico pistachios. Pistachio shipments for the production year are estimated at 750 million pounds which should provide $750,000 in assessment income. Income derived from handler assessments, along with interest income and funds from the Committee's authorized reserve, will be adequate to cover budgeted expenses. Funds in the reserve will be kept within the maximum limit permitted by the order, which is two production years' budgeted expenses.

The assessment rate established in this rule will continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate is effective for an indefinite period, the Committee will continue to meet prior to or during each production year to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA will evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking will be undertaken as necessary. The Committee's 2016–17 production year budget and those for subsequent production years will be reviewed and, as appropriate, approved by USDA.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 1,152 producers of pistachios in the production area and 19 handlers subject to regulation under the marketing order. The Small Business Administration defines small agricultural producers as those having annual receipts less than $750,000, and small agricultural service firms as those whose annual receipts are less than $7,500,000. (13 CFR 121.201)

Based on Committee data, it is estimated that about 53 percent of the handlers annually ship less than $7,500,000 worth of pistachios, and it is also estimated that 68 percent of the producers have annual receipts less than $750,000. Thus, the majority of handlers in the production area and more than two-thirds of the producers may be classified as small entities.

This rule decreases the assessment rate collected from handlers for the 2016–17 and subsequent production years from $0.0035 to $0.0010 per pound of pistachios handled. The Committee unanimously recommended 2016–17 expenditures of $922,500 and an assessment rate of $0.0010 per pound of assessed weight pistachios, which is $0.0025 lower than the 2015–16 rate currently in effect. The quantity of assessable pistachios for the 2016–17 production year is estimated at 750 million pounds. Thus, the $0.0010 rate should provide $750,000 in assessment income. Income derived from handler's assessments, along with interest and funds from the Committee's authorized reserve, should be adequate to cover expenses for the 2016–17 production year.

The major expenditures recommended by the Committee for the 2016–17 production year include $333,000 for salaries and benefits, $250,000 for research, and $19,500 for general and administrative expenses. Budgeted expenses for these items in the 2015–16 production year were $316,500, $560,000, and $19,500, respectively.

The assessment rate decrease is necessary to reduce expected income from an assessment rate set at $0.0035 per pound. The income from that assessment rate would result in the Committee's financial reserve being higher than is permitted under the order. The $0.0035 rate was established to provide sufficient income when the crop was expected to be approximately half of a normal crop. For these reasons, the Committee unanimously voted to decrease the assessment rate from $0.0035 to $0.0010. The income generated from the lower recommended rate combined with funds from the financial reserve should provide sufficient income to cover anticipated 2016–17 expenses and maintain the financial reserve within the limit specified under the marketing order.

Prior to arriving at this budget and assessment rate, the Committee considered information from various sources. Alternative expenditure levels were discussed, based upon the relative value of various activities to the pistachio industry. The Committee ultimately determined that the 2016–17 production year expenses of $922,500 were prudent, and the assessment income provided by the reduced rate and funds from the financial reserve would permit the committee to meet its expenses.

According to data from the National Agricultural Statistics Service, the season average producer price was $3.57 per pound of assessed weight pistachios in 2014 and $2.48 per pound in 2015. A review of historical and preliminary information pertaining to the upcoming production year indicates that the producer revenue for the 2016–17 production year could range between $1,860,000,000 and $2,677,500,000. Therefore, the estimated assessment revenue for the 2016–17 production year as a percentage of total producer revenue could range between 0.0004 and 0.00028 percent.

This action decreases the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to producers. However, decreasing the assessment rate reduces the burden on handlers, and may reduce the burden on producers. In addition, the Committee meeting was widely publicized throughout the California, Arizona, and New Mexico pistachio industry, and all interested persons were invited to attend the meetings and encouraged to participate in Committee deliberations on all issues.

Like all Committee meetings, the July 12, 2016, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Industry members also discussed various assessment rates, potential crop size, and estimated expenses at this meeting. Finally, interested persons are invited to submit comments on this interim rule, including the regulatory and informational impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0215, "Vegetable and Specialty Crop Marketing Orders." No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

This action imposes no additional reporting or recordkeeping requirements on either small or large California, Arizona, and New Mexico pistachio handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect, and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) The 2016–17 production year begins on September 1, 2016, and the order requires that the rate of assessment for each production year apply to all assessable pistachios handled during such production year; (2) the action decreases the assessment rate for assessable pistachios beginning with the 2016–17 production year; (3) handlers are aware of this action which was unanimously recommended by the Committee at a public meeting and is similar to other assessment rate actions issued in past years; and (4) this interim rule provides a 60-day comment period, and all comments timely received will be considered prior to finalization of this rule.

List of Subjects in 7 CFR Part 983

Pistachios, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 983 is amended as follows:

PART 983—PISTACHIOS GROWN IN CALIFORNIA, ARIZONA, AND NEW MEXICO

■ 1. The authority citation for 7 CFR part 983 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 983.253 is revised to read as follows:

§ 983.253 Assessment rate.

On and after September 1, 2016, an assessment rate of $0.0010 per pound is established for California, Arizona, and New Mexico pistachios.

Dated: September 12, 2016.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2016–22248 Filed 9–15–16; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

12 CFR Part 217

[Docket No. R–1529; RIN 7100 AE–43]

Regulatory Capital Rules: The Federal Reserve Board's Framework for Implementing the U.S. Basel III Countercyclical Capital Buffer

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final policy statement.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a final policy statement (Policy Statement) describing the framework that the Board will follow under its Regulation Q in setting the amount of the U.S. countercyclical capital buffer for advanced approaches bank holding companies, savings and loan holding companies, and state member banks.

DATES: The Policy Statement is effective October 14, 2016.

FOR FURTHER INFORMATION CONTACT: William Bassett, Deputy Associate Director, (202) 736–5644, or Rochelle Edge, Deputy Associate Director, (202) 452–2339, Division of Financial Stability; Sean Campbell, Associate Director, (202) 452–3760, Division of Banking Supervision and Regulation; Benjamin W. McDonough, Special Counsel, (202) 452–2036, Mark Buresh, Senior Attorney, (202) 452–5270, or Mary Watkins, Attorney, (202) 452–3722, Legal Division.

SUPPLEMENTARY INFORMATION:

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  C. Regulatory Flexibility Act Analysis

I. Background

In December 2015, the Board invited public comment on a proposed policy statement describing the framework that the Board would use to set the amount of the U.S. countercyclical capital buffer (CCyB) under the Board's capital rules (Regulation Q).[1] The CCyB is a macroprudential policy tool that the Board can increase during periods of rising vulnerabilities in the financial system and reduce when vulnerabilities recede or when the release of the CCyB would promote financial stability.[2] The CCyB supplements the minimum capital requirements and other capital buffers included in Regulation Q, which themselves are designed to provide substantial resilience to unexpected losses created by normal fluctuations in economic and financial conditions.

The proposed policy statement outlined the factors the Board would consider in setting the level of the CCyB, and the indicators it would monitor to help determine whether an adjustment to the CCyB is appropriate. The proposed policy statement also described the effects the Board will monitor in determining whether the CCyB is achieving the desired purposes of the CCyB.

The Board received two comments on the proposed policy statement. Commenters raised concerns about the process that the Board would follow in setting the CCyB pursuant to the policy statement, the potential economic impact of the CCyB, and the efficacy and appropriateness of the CCyB as a policy tool. Commenters also made various specific suggestions as to the indicators and standards that the Board should consider in determining whether to activate the CCyB.

After reviewing comments, the Board is revising the final Policy Statement to clarify the following key items: (1) That the Board expects that the CCyB will be activated when systemic vulnerabilities are meaningfully above normal and that the Board generally intends to increase the CCyB gradually, (2) that the Board expects to remove or reduce the CCyB when the conditions that led to its activation abate or lessen and when the release of CCyB capital would promote financial stability. The discussion in Sections II and IV below responds to comments on the proposal regarding the Board's process for setting the CCyB. In particular, as indicated below, the Board would seek comment on any proposed change to the CCyB amount and include a discussion of the reasons for the change.

II. Purpose of CCyB

The CCyB is designed to increase the resilience of large banking organizations when the Board sees an elevated risk of above-normal losses. Increasing the resilience of large banking organizations should, in turn, improve the resilience of the broader financial system. Above-normal losses often follow periods of rapid asset price appreciation or credit growth that are not well supported by underlying economic fundamentals. As stated in the proposed policy statement, the circumstances in which the Board would most likely use the CCyB as a supplemental, macroprudential tool to augment minimum capital requirements and other capital buffers would be to address circumstances when systemic vulnerabilities are somewhat above normal. By requiring institutions to hold a larger capital buffer during periods when systemic risk is increasing and reducing the buffer requirement as vulnerabilities diminish, the CCyB also has the potential to moderate fluctuations in the supply of credit over time.

The CCyB functions as an expansion of the Capital Conservation Buffer (CCB), which is applicable to all banking organizations subject to Regulation Q. To avoid limits on capital distributions and certain discretionary bonus payments,[3] the CCB requires that a banking organization hold a buffer of common equity tier 1 capital that is at least 2.5 percent of the risk-weighted assets in addition to the minimum risk-based capital ratios. The CCB is divided into quartiles, each associated with increasingly stringent limitations on capital distributions and certain discretionary bonus payments as the firm's risk-based capital ratios approach regulatory minimums.[4] The CCyB is an additional, countercyclical buffer that has the same limitations on dividends and capital distributions as the CCB.

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[1] 12 CFR part 217. *See also* 81 FR 5661 (February 3, 2016).

[2] *See* 12 CFR 217.11(b). Implementation of the CCyB also helps respond to the provision in the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) that the agencies "shall seek to make such [capital] requirements countercyclical, so that the amount of capital required to be maintained by a company increases in times of economic expansion and decreases in times of economic contraction, consistent with the safety and soundness of the company." *See* 12 U.S.C. 1467a; 12 U.S.C. 1844; 12 U.S.C. 3907 (as amended by section 616 of the Dodd-Frank Act).

[3] 12 CFR 217.11(b)(1)(i).

[4] 12 CFR 217.11(a).

The CCyB was introduced for large, internationally active banking organizations (advanced approaches institutions) in June 2013 as part of the revised regulatory capital rules issued by the Board in coordination with the Office of the Comptroller of the Currency (OCC) and the Federal Deposit Insurance Corporation (FDIC).[5] The Board's CCyB rule applies to bank holding companies, savings and loan holding companies, and state member banks subject to the advanced approaches capital rules (advanced approaches institutions).[6] The advanced approaches capital rules generally apply to banking organizations with greater than $250 billion in total assets or $10 billion in on-balance-sheet foreign exposure and to any depository institution subsidiary of such banking organizations.[7]

Because the CCyB is intended to address elevated risks from activity that is not well supported by underlying economic fundamentals, the location of the activity and the economic conditions where the activity take place provide important context. Accordingly, the CCyB applies based on the location of private-sector credit exposures by national jurisdiction.[8] Specifically, the applicable CCyB amount for a banking organization is equal to the weighted average of CCyB amounts established by the Board for the national jurisdictions where the banking organization has private-sector credit exposures.[9] The CCyB amount applicable to a banking organization is weighted by jurisdiction according to the firm's risk-weighted private-sector credit exposures for a specific jurisdiction as a percentage of the firm's total risk-weighted private-sector credit exposures.[10]

Regulation Q established the initial CCyB amount with respect to private-sector credit exposures located in the United States (U.S.-based credit exposures) at zero percent.[11] The CCyB will not exceed 2.5 percent of risk-weighted assets. This cap on the CCyB will be phased in, with the maximum potential amount of the CCyB for U.S.-based credit exposures 0.625 percentage points in 2016, 1.25 percentage points in 2017, 1.875 percentage points in 2018, and 2.5 percentage points in 2019 and thereafter.[12]

In order to provide banking organizations with sufficient time to adjust to any change in the CCyB, Regulation Q provides that a determination to increase the countercyclical capital buffer amount generally will be effective 12 months from the date of announcement. However, economic conditions may warrant an earlier or later effective date.[13] For example, it may be appropriate for an increase in the countercyclical capital buffer amount to take effect 12 months from the date that the Board proposes the increase, rather than 12 months from the issuance of a final rule.

Regulation Q states that a decision by the Board to decrease the amount of the CCyB for U.S.-based credit exposures would become effective the day after the Board decides to decrease the CCyB or the earliest date permissible under applicable law or regulation, whichever is later.[14] Moreover, the amount of the CCyB for U.S.-based credit exposures will return to 0 percent 12 months after the effective date of any CCyB adjustment, unless the Board announces a decision to maintain the current amount or adjust it again before the expiration of the 12-month period.[15]

The Board expects to make decisions about the appropriate level of the CCyB on U.S.-based credit exposures jointly with the OCC and FDIC. In addition, the Board expects that the CCyB amount for U.S.-based credit exposures would be the same for covered insured depository institutions as for covered depository institution holding companies. The CCyB is designed to take into account the broad macroeconomic and financial environment in which banking organizations function and the degree to which that environment impacts the resilience of advanced approaches institutions. Therefore, the Board's determination of the appropriate level of the CCyB for U.S.-based credit exposures would be most directly linked to the condition of the overall financial environment rather than the condition of any individual banking organization. However, the impact of the CCyB requirement on a particular banking organization will vary based on the organization's particular composition of private-sector credit exposures located across national jurisdictions.

III. Description of the Final Policy Statement

The final policy statement (Policy Statement) describes the framework that the Board would follow in setting the amount of the CCyB for U.S.-based credit exposures. The framework consists of a set of principles for translating assessments of financial system vulnerabilities that are regularly undertaken at the Board into the appropriate level of the CCyB. Those assessments are informed by a broad array of quantitative indicators of financial and economic performance and a set of empirical models. In addition, the framework includes a discussion of how the Board would assess whether the CCyB is the most appropriate policy instrument (among available policy instruments) to address the highlighted financial system vulnerabilities.

The Policy Statement is organized as follows. Section 1 provides background on the Policy Statement. Section 2 is an outline of the Policy Statement and describes its scope. Section 3 provides a broad description of the objectives of the CCyB, including a description of the ways in which the CCyB is expected to protect large banking organizations and the broader financial system. Section 4 provides a broad description of the factors that the Board considers in setting the CCyB, including specific financial system vulnerabilities and types of quantitative indicators of financial and economic performance, and outlines of empirical models the Board may use as inputs to that decision. Further, section 4 describes a set of principles that the Board expects to use for combining judgmental assessments with quantitative indicators to determine the appropriate level of the CCyB. Section 5 discusses how the Board will communicate the level of the CCyB and any changes to the CCyB. Section 6 describes how the Board plans to monitor the effects of the CCyB, including what indicators and effects will be monitored.

The Board has revised the Policy Statement to clarify that (1) the Board expects that the CCyB will be activated when systemic vulnerabilities are meaningfully above normal and the Board generally intends to increase the CCyB gradually, and (2) the Board expects to remove or reduce the CCyB when the conditions that led to its activation abate or lessen and when release of CCyB capital would promote financial stability. These changes were made to sections 1, 3, and 4. In addition, minor clarifying and technical edits were made throughout the Policy Statement.

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[5] *See* 78 FR 62018 (October 11, 2013) (Board and OCC); 79 FR 20754 (April 14, 2014) (FDIC). The Board's Regulation Q applies generally to bank holding companies with more than $1 billion in total consolidated assets and savings and loan holding companies with more than $1 billion in total consolidated assets that are not substantially engaged in commercial or insurance underwriting activities. *See* 12 CFR 217.1(c)(1).

[6] An advanced approaches institution is subject to the CCyB regardless of whether it has completed the parallel run process and received notification from its primary Federal supervisor pursuant to section 217.121(d) of Regulation Q.

[7] 12 CFR 217.100(b)(1).

[8] 12 CFR 217.11(b)(1). The Board may adjust the CCyB amount to reflect decisions made by foreign jurisdictions. *See* 12 CFR 217.11(b)(3).

[9] 12 CFR 217.11(b)(1).

[10] *Id.*

[11] The Board affirmed the CCyB amount at the current level of 0 percent contemporaneously with issuance of the proposed policy statement. *See* *http://www.federalreserve.gov/newsevents/press/bcreg/20151221b.htm.*

[12] 12 CFR 217.300(a)(2).

[13] 12 CFR 217.11(b)(2)(v)(A).

[14] 12 CFR 217.11(b)(2)(v)(B).

[15] 12 CFR 217.11(b)(2)(vi).

IV. Changes To Address Comments on the Proposal

As noted, the Board received two comments regarding the proposed policy statement. Commenters expressed concerns about the process that the Board would follow in setting the CCyB pursuant to the Policy Statement, the potential economic impact of the CCyB, and the appropriate uses of the CCyB.

A. Comments Regarding the Board's Process for Setting the CCyB

Commenters expressed concern that the Board would apply the CCyB without completing the procedures required by the Administrative Procedure Act (APA).[16] In particular, commenters argued that notice and comment rulemaking procedures should be used to increase the CCyB above zero, and for each future increase.

The Board's rule implementing the CCyB specifically provides that the Board will adjust the CCyB amount in accordance with applicable law.[17] In accordance with this provision of its rules, the Board expects to set the level of the CCyB above zero through a public notice and comment rulemaking, or through an order issued in accordance with the APA that provides each affected institution with actual notice and an opportunity for comment. In setting the level of the CCyB above zero through a public rulemaking, the Board generally expects that the notice and comment period would be at least 30 days. The Policy Statement is intended to provide insight on the framework that the Board will use to determine the appropriate level of the CCyB, not to alter procedures necessary to increase the CCyB in the future.

A commenter suggested that the Board should commit to act jointly with the OCC and FDIC in any decision to activate the CCyB. Consistent with Regulation Q and the proposal, the Board expects that any decision to adjust the CCyB will be made jointly by the OCC, FDIC, and Board. However, the Board will make decisions regarding the appropriate amount of the CCyB for the firms that it supervises based on its judgment of the facts and circumstances presented.

A commenter argued that the Board generally should not reciprocate decisions by foreign jurisdictions regarding the level of the CCyB in such jurisdictions. If the Board did decide to incorporate CCyB decisions of foreign jurisdictions, the commenter argued that the Board should implement a de minimis threshold below which U.S. banking organizations would not have to recognize the CCyB established in the foreign jurisdiction. The Policy Statement describes the framework that the Board will follow in determining the CCyB for U.S. private-sector credit exposures. The Board will address separately CCyB adjustments made by foreign jurisdictions as needed.

B. Comments Regarding the Calibration of, Inputs Into, and Impact of the CCyB

A commenter argued that the CCyB should be increased only when credit growth was considered excessive, rather than when systemic vulnerabilities were somewhat above normal, as suggested by the proposal.

The CCyB is a macroprudential policy tool intended to strengthen banking organizations' resilience against the build-up of systemic vulnerabilities and reduce fluctuations in the supply of credit. As stated in the proposed policy statement, activation of the CCyB at a time when systemic vulnerabilities are somewhat above normal reflects the prophylactic and countercyclical goals of this tool as well as the process and 12-month phase-in period that generally applies before any activation of the CCyB amount would take effect. Moreover, activation of the CCyB at a time when systemic vulnerabilities are somewhat above normal rather than delaying until systemic vulnerabilities are excessive would allow gradual increases in the CCyB, which would provide additional flexibility (over and above the 12-month phase-in period) to banking organizations as they adjust to any increases. That is, activation of the CCyB at a time when systemic vulnerabilities are somewhat above normal would likely not be associated with an activation of the CCyB to the upper end of its possible range. Further, the Board considers "systemic vulnerabilities" to be the appropriate reference point because the CCyB could be an effective tool in addressing a variety of financial system vulnerabilities, not merely credit growth.

To further clarify when the Board would expect to increase the CCyB, the Policy Statement has been modified to state that the CCyB would be increased when systemic vulnerabilities are "meaningfully above normal." For these purposes "meaningfully above normal" would reflect an assessment by the Board that financial system vulnerabilities were above normal and were either already at, or expected to build to, levels sufficient to generate material unexpected losses in the event of an unfavorable development in financial markets or the economy. The text in the policy statement has also been modified to clarify that systemic vulnerabilities being meaningfully above normal would correspond to the Board beginning to increase the CCyB above zero and to provide additional discussion of when and how the Board would deactivate or reduce the CCyB.

Commenters argued that the Board should conduct and release analyses of the economic impact and costs and benefits of the CCyB in connection with the proposed policy statement as well as with any decision to increase the level of the CCyB. Commenters contended that such analyses should take into account other existing prudential regulation, including other regulatory capital requirements, and consider whether alternative policy tools may be more effective for a particular situation. The commenters expressed concern that there could be material adverse economic consequences to activation of the CCyB. Similarly, one commenter argued that the Board should conduct a comprehensive analysis of the costs and benefits of regulatory capital requirements, including the CCyB, as well as prudential liquidity regulations and regulations established by other agencies.

Commenters also argued that the Board should provide additional detail regarding the data, models, and metrics that would inform a decision to activate the CCyB, as well as the standards that would be applied to determine the calibration of the CCyB. Additionally, commenters raised issues with certain of the indicators identified in the Policy Statement. For instance, a commenter cautioned that no academic consensus had been reached with regard to the usefulness of a credit-to-GDP ratio gap as an indicator of economic conditions.

The final Policy Statement provides additional information to the public regarding the framework that the Board will follow in setting the CCyB. The Policy Statement itself does not change either the CCyB or the capital requirements applicable to advanced approaches banking organizations. As described above, the Board generally would expect to provide notice to the public and seek comment on the proposed level of the CCyB as part of making any final determination to change the CCyB. Any proposed change in the level of the CCyB would include a discussion of the reasons for the proposed action as determined by the particular circumstances.

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[16] 5 U.S.C. 551 *et seq.*

[17] 12 CFR 217.11(b)(2)(ii).

One commenter stated that the FFIEC 009 reporting form requires firms to report information that is not aligned with the information needed to determine the CCyB amount applicable to a firm and that the Board should amend the FFIEC 009 to align with CCyB in order to reduce burden. The Board may consider reporting for purposes of the CCyB at a later date.

The Board recognizes that no single data point or indicator can provide a comprehensive understanding of economic conditions or systemic vulnerabilities. The items for consideration listed in the Policy Statement are a non-exclusive list of quantitative and qualitative indicators that may inform the Board's assessment of economic conditions and determinations regarding the appropriate level of the CCyB. As explained in the proposed and final Policy Statement, some academic research has shown the credit-to-GDP ratio to be useful in identifying periods of financial excess followed by a period of crisis. However, the Board does not expect this indicator to be used in isolation. Furthermore, as noted, any proposal to increase the CCyB will include a discussion of the indicators informing the proposal, and will seek comment on the interpretation of these indicators. As noted above, the Board expects that the types of indicators and models considered will evolve over time, based on advances in research and the experience of the Board with this tool.

Commenters argued that the CCyB would not be effective in containing asset bubbles or excessive credit risks because these tend to occur within sectors as opposed to across the financial system equally. A commenter suggested that targeted guidance for particular sectors would likely be more effective at containing risks of this type than a broad based capital charge imposed by the CCyB.

Commenters also argued that the CCyB would not be effective in addressing many systemic vulnerabilities because it applies only to advanced approaches banking organizations, which, while significant, represent a relatively small percentage of the total provision of credit in the U.S. economy. A commenter contended that activation of the CCyB might exacerbate risk in the financial system by shifting lending activity away from large and closely regulated commercial banks and into the shadow banking system. In addition, a commenter argued that advanced approaches banking organizations were subject to significant capital, liquidity, and other prudential requirements such that they were likely to be resilient in the event of adverse economic conditions. As a result, the commenter argued, advanced approaches banking organizations were unlikely to be made materially more resilient as a result of imposition of the CCyB.

As reflected in the Policy Statement, the pace and magnitude of changes in the CCyB will depend on the underlying conditions in the financial sector and the economy, the desired effects of the proposed change in the CCyB, and consideration of whether the CCyB is the most appropriate of the Board's available policy instruments to address the financial system vulnerabilities. A natural corollary to this analysis would be consideration of whether the CCyB could be expected to increase other systemic vulnerabilities. The CCyB is one of several policy tools available to the Board. In determining whether or not to change the CCyB, the Board will consider whether the CCyB is the most appropriate of available policy tools, and whether the CCyB would be most effective if used in conjunction with other policy tools.

V. Administrative Law Matters

A. Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act (Pub. L. 106–102, 113 Stat. 1338, 1471, 12 U.S.C. 4809) requires the Federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The Board received no comments on the use of plain language.

B. Paperwork Reduction Act Analysis

In accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3506), the Board has reviewed the Policy Statement to assess any information collections. There are no collections of information as defined by the Paperwork Reduction Act in the proposal.

C. Regulatory Flexibility Act Analysis

The Board is providing a final regulatory flexibility analysis with respect to this Policy Statement. The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* (RFA), generally requires that an agency provide a regulatory flexibility analysis in connection with a final rulemaking.

The Board sought comment on whether the proposal would impose undue burdens on, or have unintended consequences for, small banking organizations. The Board received one comment on this aspect of the proposal, which argued that the Board's initial regulatory flexibility analysis was flawed in asserting that small banking organizations would not be affected by the proposal because of the broader impact that the CCyB could have on lending and economic growth in general.

This Policy Statement will be added as an appendix to Regulation Q to describe the framework that the Board will follow in setting the amount of the CCyB for U.S.-based credit exposures. The CCyB only applies to bank holding companies, savings and loan holding companies, and state member banks that are advanced approaches Board-regulated institutions for purposes of the Board's Regulation Q (advanced approaches banking organizations). The Regulatory Flexibility Act requires consideration only of the impact of the proposed rule on small entities that are subject to the requirements of the rule, as opposed to small entities indirectly affected by the rule through its impact on the national economy.[18] Generally, advanced approaches banking organizations are those with total consolidated assets of $250 billion or more, that have total consolidated on-balance sheet foreign exposures of $10 billion or more, that have subsidiary depository institutions that are advanced approaches institutions, or that elect to use the advanced approaches framework.[19] Under regulations issued by the Small Business Administration, a small entity includes a depository institution, bank holding company, or savings and loan holding company with assets of $550 million or less (small banking organizations).[20] As of June 30, 2016, there were approximately 3,204 small bank holding companies, 157 small savings and loan holding companies, and 594 small state member banks. Banking organizations that are subject to the final rule therefore are expected to substantially exceed the $550 million asset threshold at which a banking entity would qualify as a small bank holding company. As a result, the final rule is not expected to apply directly to any small banking organizations for purposes of the RFA.

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[18] *See e.g., Aeronautical Repair Station Association* v. *Federal Aviation Administration,* 494 F.3d 161, 174–178 (D.C. Cir. 2007).

[19] *See* 12 CFR 217.100.

[20] *See* 13 CFR 121.201. Effective July 14, 2014, the Small Business Administration revised the size standards for banking organizations to $550 million in assets from $500 million in assets. 79 FR 33647 (June 12, 2014). The Small Business Administration's June 12, 2014, interim final rule was adopted without change as a final rule by the Small Business Administration on January 12, 2016. 81 FR 3949 (January 25, 2016).

Therefore, there are no significant alternatives to the final rule that would have less economic impact on small bank holding companies. As discussed above, there are no projected reporting, recordkeeping, and other compliance requirements of the final rule. The Board does not believe that the final rule duplicates, overlaps, or conflicts with any other Federal rules. In light of the foregoing, the Board does not believe that the final rule would have a significant economic impact on a substantial number of small entities.

In light of the foregoing, the Board does not believe that the final rule will have a significant impact on small entities.

List of Subjects in 12 CFR Part 217

Administrative practice and procedure, Banks, banking. Holding companies, Reporting and recordkeeping requirements, Securities.

Authority and Issuance

For the reasons stated in the preamble, the Board of Governors of the Federal Reserve System amends 12 CFR part 217 as follows:

PART 217—CAPITAL ADEQUACY OF BANK HOLDING COMPANIES, SAVINGS AND LOAN HOLDING COMPANIES, AND STATE MEMBER BANKS (REGULATION Q)

■ 1. The authority citation for part 217 continues to read as follows:

Authority: 12 U.S.C. 248(a), 321–338a, 481–486, 1462a, 1467a, 1818, 1828, 1831n, 1831o, 1831p–l, 1831w, 1835, 1844(b), 1851, 3904, 3906–3909, 4808, 5365, 5368, 5371.

■ 2. Appendix A to part 217 is added to read as follows:

Appendix A to Part 217—The Federal Reserve Board's Framework for Implementing the Countercyclical Capital Buffer

1. Background

(a) In 2013, the Board of Governors of the Federal Reserve System (Board) issued a final regulatory capital rule (Regulation Q) in coordination with the Office of the Comptroller of the Currency (OCC) and the Federal Deposit Insurance Corporation (FDIC) that strengthened risk-based and leverage capital requirements applicable to insured depository institutions and depository institution holding companies (banking organizations).[1] Among those changes was the introduction of a countercyclical capital buffer (CCyB) for large, internationally active banking organizations.[2]

(b) The CCyB is a supplemental, macroprudential policy tool that the Board can increase during periods of rising vulnerabilities in the financial system and reduce when vulnerabilities recede. It is designed to increase the resilience of large banking organizations when there is an elevated risk of above-normal losses. Increasing the resilience of large banking organizations will, in turn, improve the resilience of the broader financial system. Above-normal losses often follow periods of rapid asset price appreciation or credit growth that are not well supported by underlying economic fundamentals. The circumstances in which the Board would most likely begin to increase the CCyB above zero percent to augment minimum capital requirements and other capital buffers would be when systemic vulnerabilities are meaningfully above normal. By requiring large banking organizations to hold additional capital during those periods of excess and removing the requirement to hold additional capital when the vulnerabilities have diminished, the CCyB also is expected to moderate fluctuations in the supply of credit over time. Moderating the supply of credit may mitigate or prevent the conditions that contribute to above-normal losses, such as elevated asset prices and excessive leverage, and prevent or mitigate reductions in lending to creditworthy borrowers that can amplify an economic downturn. In this way, implementation of the CCyB also responds to the Dodd-Frank Act's requirement that the Board seek to make its capital requirements countercyclical.[3]

(c) Regulation Q established the initial CCyB amount with respect to private sector credit exposures located in the United States (U.S.-based credit exposures) at zero percent and provided that the maximum potential amount of the CCyB for credit exposures in the United States was 2.5 percent of risk-weighted assets.[4] The Board expects to make decisions about the appropriate level of the CCyB for U.S.-based credit exposures jointly with the OCC and FDIC, and expects that the CCyB amount for U.S.-based credit exposures will be the same for covered depository institution holding companies and insured depository institutions. The CCyB is designed to take into account the macrofinancial environment in which banking organizations function and the degree to which that environment impacts the resilience of advanced approaches institutions. Therefore, the appropriate level of the CCyB for U.S.-based credit exposures is not closely linked to the characteristics of an individual institution. Rather, the impact of the CCyB on any single institution will depend on the particular composition of the private-sector credit exposures of the institution across national jurisdictions.

2. Overview and Scope of the Policy Statement

This Policy Statement describes the framework that the Board will follow in setting the amount of the CCyB for U.S.-based credit exposures. The framework consists of a set of principles for translating assessments of financial system vulnerabilities that are regularly undertaken by the Board into the appropriate level of the CCyB. Those assessments are informed by a broad array of quantitative indicators of financial and economic performance and a set of empirical models. In addition, the framework includes an assessment of whether the CCyB is the most appropriate policy instrument (among available policy instruments) to address the highlighted financial system vulnerabilities.

3. The Objectives of the CCyB

(a) The objectives of the CCyB are to strengthen banking organizations' resilience against the build-up of systemic vulnerabilities and reduce fluctuations in the supply of credit. The CCyB supplements the minimum capital requirements and the capital conservation buffer, which themselves are designed to provide substantial resilience to unexpected losses created by normal fluctuations in economic and financial conditions. The capital surcharge on global systemically important banking organizations adds an additional layer of defense for the largest and most systemically important institutions, whose financial distress can have outsized effects on the rest of the financial system and the real economy.[5] However, periods of financial excesses, for example as reflected in episodes of rapid asset price appreciation or credit growth not well supported by underlying economic fundamentals, are often followed by above-normal losses that leave banking organizations and other financial institutions undercapitalized. Therefore, the Board would most likely begin to increase the CCyB above zero in those circumstances when systemic vulnerabilities become meaningfully above normal and progressively raise the CCyB level if vulnerabilities become more severe.

(b) The CCyB is expected to help provide additional resilience for advanced approaches institutions, and by extension the broader financial system, against elevated vulnerabilities primarily in two ways. First, advanced approaches institutions will likely hold more capital to avoid limitations on capital distributions and discretionary bonus payments resulting from implementation of the CCyB. Strengthening their capital positions when financial conditions are accommodative would increase the capacity of advanced approaches institutions to absorb outsized losses during a future significant economic downturn or period of financial instability, thus making them more resilient.

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[1] *See 12 CFR part 217; Federal Reserve Board Approves Final Rule To Help Ensure Banks Maintain Strong Capital Positions (July 2, 2013), available at http://www.federalreserve.gov; Agencies Adopt Supplementary Leverage Ratio Notice of Proposed Rulemaking (July 9, 2013), available at http://www.occ.gov; and FDIC Board Approves Basel III Interim Final Rule and Supplementary Leverage Ratio Notice of Proposed Rulemaking (July 9, 2013) available at https://www.fdic.gov.*

[2] 12 CFR 217.11(b). The CCyB applies only to banking organizations subject to the advanced approaches capital rules, which generally apply to those banking organizations with greater than $250 billion in assets or more than $10 billion in on-balance-sheet foreign exposures. *See* 12 CFR 217.100(b). An advanced approaches institution is subject to the CCyB regardless of whether it has completed the parallel run process and received notification from its primary Federal supervisor. *See* 12 CFR 217.121(d).

[3] 12 U.S.C. 1844(b), 1464a(g)(1), and 3907(a)(1) (codifying sections 616(a), (b), and (c) of the Dodd-Frank Act).

[4] The CCyB is subject to a phase-in arrangement between 2016 and 2019. *See* 12 CFR 217.300(a)(2).

[5] *See, Federal Reserve Board Approves Final Rule Requiring The Largest, Most Systemically Important U.S. Bank Holding Companies To Further Strengthen Their Capital Positions (July 20, 2015), available at http://www.federalreserve.gov.*

(c) The second and related goal of the CCyB is to promote a more sustainable supply of credit over the economic cycle. During a credit cycle downturn, better-capitalized institutions have been shown to be more likely than weaker institutions to have continued access to funding. Better-capitalized institutions also are less likely to take actions that lead to broader financial-sector distress and its associated macroeconomic costs, such as large-scale sales of assets at prices below their fundamental value and sharp contractions in credit supply.[6] Therefore, it is likely that as a result of the CCyB having been put into place during the preceding period of rapid credit creation, advanced approaches institutions would be better positioned to continue their important intermediary functions during a subsequent economic contraction. A timely and credible reduction in the CCyB requirement during a period of high credit losses could reinforce those beneficial effects of a higher base level of capital, because it would permit advanced approaches institutions either to realize loan losses promptly and remove them from their balance sheets or to expand their balance sheets, for example by continuing to lend to creditworthy borrowers.

(d) During a period of cyclically increasing vulnerabilities, advanced approaches institutions might react to an increase in the CCyB by raising lending standards, otherwise reducing their risk exposure, augmenting their capital, or some combination of those actions. They may choose to raise capital by taking actions that would increase net income, reducing capital distributions such as share repurchases or dividends, or issuing new equity. In this regard, an increase in the CCyB would not prevent advanced approaches institutions from maintaining their important role as credit intermediaries, but would reduce the likelihood that banking organizations with insufficient capital would foster unsustainable credit growth or engage in imprudent risk taking. The specific combination of adjustments and the relative size of each adjustment will depend in part on the initial capital positions of advanced approaches institutions, the cost of debt and equity financing, and the earnings opportunities presented by the economic situation at the time.[7]

4. The Framework for Setting the U.S. CCyB

(a) The Board regularly monitors and assesses threats to financial stability by synthesizing information from a comprehensive set of financial-sector and macroeconomic indicators, supervisory information, surveys, and other interactions with market participants.[8] In forming its view about the appropriate size of the U.S. CCyB, the Board will consider a number of financial system vulnerabilities, including but not limited to, asset valuation pressures and risk appetite, leverage in the nonfinancial sector, leverage in the financial sector, and maturity and liquidity transformation in the financial sector. The decision will reflect the implications of the assessment of overall financial system vulnerabilities as well as any concerns related to one or more classes of vulnerabilities. The specific combination of vulnerabilities is important because an adverse shock to one class of vulnerabilities could be more likely than another to exacerbate existing pressures in other parts of the economy or financial system.

(b) The Board intends to monitor a wide range of financial and macroeconomic quantitative indicators including, but not limited to, measures of relative credit and liquidity expansion or contraction, a variety of asset prices, funding spreads, credit condition surveys, indices based on credit default swap spreads, option implied volatilities, and measures of systemic risk.[9] In addition, empirical models that translate a manageable set of quantitative indicators of financial and economic performance into potential settings for the CCyB, when used as part of a comprehensive judgmental assessment of all available information, can be a useful input to the Board's deliberations. Such models may include, but are not limited to, those that rely on small sets of indicators—such as the nonfinancial credit-to-GDP ratio, its growth rate, and combinations of the credit-to-GDP ratio with trends in the prices of residential and commercial real estate—which some academic research has shown to be useful in identifying periods of financial excess followed by a period of crisis on a cross-country basis.[10] Such models may also include those that consider larger sets of indicators, which have the advantage of representing conditions in all key sectors of the economy, especially those specific to risk-taking, performance, and the financial condition of large banks.[11]

(c) However, no single indictor or fixed set of indicators can adequately capture all the vulnerabilities in the U.S. economy and financial system. Moreover, adjustments in the CCyB that were tightly linked to a specific model or set of models could be imprecise due to the relatively short period that some indicators are available, the limited number of past crises against which the models can be calibrated, and limited experience with the CCyB as a macroprudential tool. As a result, the types of indicators and models considered in assessments of the appropriate level of the CCyB are likely to change over time based on advances in research and the experience of the Board with this new macroprudential tool.

(d) The Board will determine the appropriate level of the CCyB for U.S.-based credit exposures based on its analysis of the above factors. Generally, a zero percent U.S. CCyB amount would reflect an assessment that U.S. economic and financial conditions are broadly consistent with a financial system in which levels of system-wide vulnerabilities are within or near their normal range of values. The Board could increase the CCyB as vulnerabilities build. A 2.5 percent CCyB amount for U.S.-based credit exposures, which is the maximum level under the Board's rule, would reflect an assessment that the U.S. financial sector is experiencing a period of significantly elevated or rapidly increasing system-wide vulnerabilities. Importantly, as a macroprudential policy tool, the CCyB will be activated and deactivated based on broad developments and trends in the U.S. financial system, rather than the activities of any individual banking organization.

(e) Similarly, the Board would remove or reduce the CCyB when the conditions that led to its activation abate or lessen. Additionally, the Board would remove or reduce the CCyB when release of CCyB capital would promote financial stability. Indeed, for the CCyB to be most effective, the CCyB should be deactivated or reduced in a timely manner. Deactivating the CCyB in a timely manner could, for example, promote the prompt realization of loan losses by advanced approaches institutions and the removal of such loans from their balance sheets and would reduce the likelihood that advanced approaches institutions would significantly pare their risk-weighted assets in order to maintain their capital ratios during a downturn.

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[6] For additional background on the relationship between financial distress and economic outcomes, see Carmen Reinhart and Kenneth Rogoff (2009), *This Time is Different*. Princeton University Press; Òscar Jordà & Moritz Schularick & Alan M Taylor (2011), "Financial Crises, Credit Booms, and External Imbalances: 140 Years of Lessons," *IMF Economic Review*, Palgrave Macmillan, vol. 59(2), pages 340–378; and Bank for International Settlements (2010), "Assessing the Long-Run Economic Impact of Higher Capital and Liquidity Requirements."

[7] For estimates of the size of certain adjustments, see Samuel G. Hanson, Anil K. Kashyap, and Jeremy C. Stein (2011), "A Macroprudential Approach to Financial Regulation," *Journal of Economic Perspectives* 25(1), pp. 3–28; Skander J. Van den Heuvel (2008), "The Welfare Cost of Bank Capital Requirements." *Journal of Monetary Economics* 55, pp. 298–320.

[8] Tobias Adrian, Daniel Covitz, and Nellie Liang (2014), "Financial Stability Monitoring." *Finance and Economics Discussion Series* 2013–021. Washington: Board of Governors of the Federal Reserve System, *http://www.federalreserve.gov/pubs/feds/2013/201321/201321pap.pdf.*

[9] *See* 12 CFR 217.11(b)(2)(iv).

[10] *See, e.g.*, Jorda, Oscar, Moritz Schularick and Alan Taylor, 2013. "When Credit Bites Back: Leverage, Business Cycles and Crises," *Journal of Money, Credit, and Banking*, 45(2), pp. 3–28, and Drehmann, Mathias, Claudio Borio, and Kostas Tsatsaronis, 2012. "Characterizing the Financial Cycle: Don't Lose Sight of the Medium Term!" BIS Working Papers 380, Bank for International Settlements. Jorda, Oscar, Moritz Schularick and Alan Taylor, 2015. "Leveraged Bubbles," *Center for Economic Policy Research Discussion Paper* No. DP10781. BCBS (2010), "Guidance for National Authorities Operating the Countercyclical Capital Buffer," BIS.

[11] *See, e.g.*, Aikman, David, Michael T. Kiley, Seung Jung Lee, Michael G. Palumbo, and Missaka N. Warusawitharana (2015), "Mapping Heat in the U.S. Financial System," *Finance and Economics Discussion Series* 2015–059. Washington: Board of Governors of the Federal Reserve System, *http://dx.doi.org/10.17016/FEDS.2015.059* (providing an example of the range of indicators used and type of analysis possible).

(f) The pace and magnitude of changes in the CCyB will depend importantly on the underlying conditions in the financial sector and the economy as well as the desired effects of the proposed change in the CCyB. If vulnerabilities are rising gradually, then incremental increases in the level of the CCyB may be appropriate. Incremental increases would allow banks to augment their capital primarily through retained earnings and allow policymakers additional time to assess the effects of the policy change before making subsequent adjustments. However, if vulnerabilities in the financial system are building rapidly, then larger or more frequent adjustments may be necessary to increase loss-absorbing capacity sooner and potentially to mitigate the rise in vulnerabilities.

(g) The Board will also consider whether the CCyB is the most appropriate of its available policy instruments to address the financial system vulnerabilities highlighted by the framework's judgmental assessments and empirical models. The CCyB primarily is intended to address cyclical vulnerabilities, rather than structural vulnerabilities that do not vary significantly over time. Structural vulnerabilities are better addressed through targeted reforms or permanent increases in financial system resilience. Two central factors for the Board to consider are whether advanced approaches institutions are exposed—either directly or indirectly—to the vulnerabilities identified in the comprehensive judgmental assessment or by the quantitative indicators that suggest activation of the CCyB and whether advanced approaches institutions are contributing—either directly or indirectly—to these highlighted vulnerabilities.

(h) In setting the CCyB for advanced approaches institutions that it supervises, the Board plans to consult with the OCC and FDIC on their analyses of financial system vulnerabilities and on the extent to which advanced approaches banking organizations are either exposed to or contributing to these vulnerabilities.

5. Communication of the U.S. CCyB With the Public

(a) The Board expects to consider at least once per year the applicable level of the U.S. CCyB. The Board will review financial conditions regularly throughout the year and may adjust the CCyB more frequently as a result of those monitoring activities.

(b) Further, the Board will continue to communicate with the public in other formats regarding its assessment of U.S. financial stability, including financial system vulnerabilities. In the event that the Board considered that a change in the CCyB were appropriate, it would, in proposing the change, include a discussion of the reasons for the proposed action as determined by the particular circumstances. In addition, the Board's biannual Monetary Policy Report to Congress, usually published in February and July, will continue to contain a section that reports on developments pertaining to the stability of the U.S. financial system.[12] That portion of the report will be an important vehicle for updating the public on how the Board's current assessment of financial system vulnerabilities bears on the setting of the CCyB.

6. Monitoring the Effects of the U.S. CCyB

(a) The effects of the U.S. CCyB ultimately will depend on the level at which it is set, the size and nature of any adjustments in the level, and the timeliness with which it is increased or decreased. The extent to which the CCyB may affect vulnerabilities in the broader financial system depends upon a complex set of interactions between required capital levels at the largest banking organizations and the economy and financial markets. In addition to the direct effects, the secondary economic effects could be amplified if financial markets extract a signal from the announcement of a change in the CCyB about subsequent actions that might be taken by the Board. Moreover, financial market participants might react by updating their expectations about future asset prices in specific markets or broader economic activity based on the concerns expressed by the regulators in communications announcing a policy change.

(b) The Board will monitor and analyze adjustments by banking organizations and other financial institutions to the CCyB: whether a change in the CCyB leads to observed changes in risk-based capital ratios at advanced approaches institutions, as well as whether those adjustments are achieved passively through retained earnings, or actively through changes in capital distributions or in risk-weighted assets. Other factors to be monitored include the extent to which loan growth and interest rate spreads on loans made by affected banking organizations change relative to loan growth and loan spreads at banking organizations that are not subject to the buffer. Another consideration in setting the CCyB and other macroprudential tools is the extent to which the adjustments by advanced approaches institutions to higher capital buffers lead to migration of credit market activity outside of those banking organizations, especially to the nonbank financial sector. Depending on the amount of migration, which institutions are affected by it, and the remaining exposures of advanced approaches institutions, those adjustments could cause the Board to favor either a higher or a lower value of the CCyB.

(c) The Board will also monitor information regarding the levels of and changes in the CCyB in other countries. The Basel Committee on Banking Supervision is expected to maintain this information for member countries in a publically available form on its Web site.[13] Using that data in conjunction with supervisory and publicly available datasets, the Board will be able to draw not only upon the experience of the United States but also that of other countries to refine estimates of the effects of changes in the CCyB.

By order of the Board of Governors of the Federal Reserve System, September 8, 2016.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2016–21970 Filed 9–15–16; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–6146; Directorate Identifier 2014–NM–120–AD; Amendment 39–18656; AD 2016–19–07]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2008–19–08, for all Dassault Aviation Model Falcon 10 airplanes. AD 2008–19–08 required repetitive replacement of the flexible hoses installed in the wing (slat) anti-icing system with new hoses. This new AD requires reducing the life limit of these flexible hoses, which reduces the repetitive replacement intervals. This AD was prompted by additional reports of collapse of the flexible hoses installed in the slat anti-icing systems on airplanes equipped with new, improved hoses. We are issuing this AD to prevent collapse of the flexible hoses in the slat anti-icing system, which could lead to insufficient anti-icing capability and, if icing is encountered in this situation, could result in reduced controllability of the airplane.

DATES: This AD is effective October 21, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 11, 2007 (72 FR 51161, September 6, 2007).

ADDRESSES: For service information identified in this final rule, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; Internet *http://www.dassaultfalcon.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6146.

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[12] For the most recent discussion in this format, see box titled "Developments Related to Financial Stability" in Board of Governors of the Federal Reserve System, *Monetary Policy Report to Congress,* June 2016, pp. 20–21.

[13] BIS, Countercyclical capital buffer (CCyB), *www.bis.org/bcbs/ccyb/index.htm.*

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6146; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (telephone 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1137; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2008–19–08, Amendment 39–15675 (73 FR 54492, September 22, 2008) (“AD 2008–19–08”). AD 2008–19–08 applied to all Dassault Aviation Model Falcon 10 airplanes. The NPRM published in the **Federal Register** on May 3, 2016 (81 FR 26495) (“the NPRM”). The NPRM was prompted by additional reports of collapse of the flexible hoses installed in the slat anti-icing systems on airplanes equipped with new, improved hoses. The NPRM proposed to continue to require repetitive replacement of the flexible hoses installed in the wing (slat) anti-icing system with new hoses. The NPRM also proposed to require reducing the life limit of these flexible hoses, which would reduce the repetitive replacement intervals. We are issuing this AD to prevent collapse of the flexible hoses in the slat anti-icing system, which could lead to insufficient anti-icing capability and, if icing is encountered in this situation, could result in reduced controllability of the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014–0104, dated May 7, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition on all Dassault Aviation Model Falcon 10 airplanes. The MCAI states:

> Occurrences were reported involving an in-service Falcon 10 aeroplane, where wing anti-ice hoses collapsed. The subsequent investigation revealed that the flexible hose, Part Number (P/N) FAL1005, collapsed because of an internal ply separation.
>
> This condition, if not corrected, could lead to failure of the ice-protection system to remove ice accretion on the wing, possibly resulting in reduced control of the aeroplane.
>
> To address this potential unsafe condition, EASA issued AD 2005–0020 and AD 2006–0114 [which correspond to AD 2008–19–08], respectively, imposing flight limitations and requiring replacement of the flexible hoses P/N FAL1005 with improved hoses P/N FAL1007.
>
> Since those [EASA] ADs were issued, further occurrences were reported concerning aeroplanes with improved hoses, which led to the conclusion that the life limit of the flexible hose P/N FAL1007 must be reduced.
>
> For the reasons above, this [EASA] AD retains the requirements of EASA AD 2006–0114, which is superseded; supersedes EASA AD 2005–0020; requires replacement of flexible hoses having P/N FAL 1000, P/N 1001, P/N FAL1005, or P/N FAL1005D, and reduces the life limit of the flexible hoses P/N 1007 [which would reduce the repetitive replacement intervals].

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6146.

Comments

We gave the public the opportunity to participate in developing this AD. We considered the comment received. The commenter, Catherine Corn, supported the NPRM.

Clarification to This AD

We have changed the “Definition of Serviceable Flexible Hose” specified in paragraph (j) of this AD from “350 flight hours or less” to “less than 350 flight hours” to clarify the intent of the flight hours for the life-limit of the flexible hose specified in paragraph (i) of this AD.

We have also revised paragraph (g) of this AD to clarify that accomplishing the replacement required by paragraph (i) of this AD terminates the replacements required by paragraph (g) of this AD.

Conclusion

We reviewed the available data, including the comment received, and determined that air safety and the public interest require adopting this AD with the change described previously, and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Costs of Compliance

We estimate that this AD affects 124 airplanes of U.S. registry.

The actions that are required by AD 2008–19–08, and retained in this AD, take about 8 work-hours per product, at an average labor rate of $85 per work-hour. Required parts cost about $880. Based on these figures, the estimated cost of the actions that are required by AD 2008–19–08 is up to $1,560 per product, per replacement cycle.

We also estimate that it takes about 4 work-hours per product to comply with the new basic requirements of this AD. The average labor rate is $85 per work-hour. Required parts will cost about $936 per product. Based on these figures, we estimate the cost of this AD on U.S. operators to be $158,224, or $1,276 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. “Subtitle VII: Aviation Programs,” describes in more detail the scope of the Agency’s authority.

We are issuing this rulemaking under the authority described in “Subtitle VII, Part A, Subpart III, Section 44701: General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2008–19–08, Amendment 39–15675 (73 FR 54492, September 22, 2008), and adding the following new AD:

2016–19–07 Dassault Aviation: Amendment 39–18656; Docket No. FAA–2016–6146; Directorate Identifier 2014–NM–120–AD.

(a) Effective Date

This AD is effective October 21, 2016.

(b) Affected ADs

This AD replaces AD 2008–19–08, Amendment 39–15675 (73 FR 54492, September 22, 2008) ("AD 2008–19–08").

(c) Applicability

This AD applies to all Dassault Aviation Model Falcon 10 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 30, Ice and Rain Protection.

(e) Reason

This AD was prompted by reports of collapse of the flexible hoses installed in the slat anti-icing systems on airplanes equipped with new, improved hoses. We are issuing this AD to prevent collapse of the flexible hoses in the slat anti-icing system, which could lead to insufficient anti-icing capability and, if icing is encountered in this situation, could result in reduced controllability of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Retained Repetitive Hose Replacement, With Revised Compliance Language

This paragraph restates the requirements of paragraph (h) of AD 2008–19–08, with revised compliance language. As of October 27, 2008 (the effective date of AD 2008–19–08): Replace the flexible hoses installed in the slat anti-icing system with new hoses having part number (P/N) FAL1007, in accordance with the Accomplishment Instructions of Dassault Service Bulletin F10–313, Revision 1, dated May 10, 2006, within 700 flight hours since the last replacement or within 100 flight hours after October 27, 2008, whichever occurs later, and thereafter at intervals not to exceed 700 flight hours. Accomplishing the replacement required by paragraph (h) or (i) of this AD ends the repetitive replacements required by this paragraph.

(h) New Requirement of This AD: Hose Replacement for Certain Part Numbers

Within 65 days after the effective date of this AD: Replace any flexible hose having part number (P/N) FAL1000, P/N FAL1001, or P/N FAL1005D with a new, improved flexible hose having P/N FAL1007, using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Dassault Aviation's EASA Design Organization Approval (DOA).

(i) Life-Limit for P/N FAL1007—Repetitive Replacements

At the later of the times specified in paragraphs (i)(1) and (i)(2) of this AD, replace any flexible hose having part number P/N FAL1007 with a serviceable flexible hose having P/N FAL1007, using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA; or Dassault Aviation's EASA DOA. Thereafter, before the accumulation of 350 flight hours on any flexible hose having P/N FAL1007, replace the flexible hose with a serviceable flexible hose having P/N FAL1007.

(1) Before the accumulation of 350 flight hours on the flexible hose P/N FAL1007 since first installation on an airplane.

(2) At the earlier of the times specified in paragraphs (i)(2)(i) and (i)(2)(ii) of this AD.

(i) Within 200 flight hours after the effective date of this AD.

(ii) Before the accumulation of 700 flight hours on the flexible hose P/N FAL1007 since first installation on an airplane, or within 65 days after the effective date of this AD, whichever occurs later.

(j) Definition of Serviceable Flexible Hose

For the purpose of this AD, a serviceable flexible hose is a flexible hose having P/N FAL1007 that has accumulated less than 350 flight hours since first installation on an airplane.

(k) Parts Installation Limitation

After accomplishing the replacement required by paragraph (h) of this AD, no person may install a flexible hose in the slat anti-icing system on any airplane, unless that hose is a serviceable flexible hose having P/N FAL1007, and thereafter repetitive hose replacements are done as required by paragraph (i) of this AD.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1137; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA; or Dassault Aviation's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(m) Related Information

Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014–0104, dated May 7, 2014, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6146.

(n) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following service information was approved for IBR on October 11, 2007, (72 FR 51161, September 62, 2007).

(i) Dassault Service Bulletin F10–313, Revision 1, dated May 10, 2006.

(ii) Reserved.

(4) For service information identified in this AD, contact Dassault Falcon Jet

Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; Internet *http://www.dassaultfalcon.com.*

(5) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(6) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on September 7, 2016.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–22177 Filed 9–15–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9108; Directorate Identifier 2016–NM–133–AD; Amendment 39–18655; AD 2016–19–06]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Airbus Model A330–200, Model A330–300, Model A340–200, and Model A340–300 series airplanes. This AD requires an inspection to determine the part number and serial number of certain escape slides on the left and right sides of the airplane, and replacement if necessary. This AD was prompted by a report indicating that the aspirator on certain escape slides might have been damaged because of incorrect packing during overhaul. We are issuing this AD to detect and correct damaged aspirators on escape slides. Failure of an aspirator to inflate an escape slide could prevent deployment of the escape slide during an emergency, possibly resulting in reduced evacuation capacity from the airplane and consequent injury to occupants.

DATES: This AD becomes effective October 3, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 3, 2016.

We must receive comments on this AD by October 31, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *airworthiness.A330-A340@airbus.com;* Internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9108.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9108; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1138; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2016–0137R1, dated July 21, 2016 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for certain Airbus Model A330–200 Freighter, Model A330–200, Model A330–300, Model A340–200, and Model A340–300 series airplanes. The MCAI states:

> It has been reported that some door 3, Type 1, escape slides Part Number (P/N) 7A1509-series may have sustained damage to the slide aspirator, due to an incorrect packing during last overhaul. This damage affects the air inlet end of the slide aspirator by either permanently deforming the inlet, or leading to cracks in the supply line to the aspirator nozzle.
>
> This condition, if not detected and corrected, could lead to failure of the slide aspirator to perform its intended function to inflate the evacuation slide, preventing slide deployment during an emergency, possibly resulting in reduced evacuation capacity from the aeroplane and consequent injury to occupants.
>
> Prompted by these findings, Airbus issued Alert Operators Transmission (AOT) A25L009–16 to provide instructions to identify and replace the affected slides.
>
> Consequently, EASA issued AD 2016–0137, requiring identification of the door 3, Type 1, slide installed on the aeroplane, and, depending on findings, the replacement of the slide with a serviceable part.
>
> Since that [EASA] AD was issued, it was identified that affected slides cannot be installed on aeroplanes embodying optional Airbus mod 40161.
>
> For the reason described above, this [EASA] AD is revised to reduce the Applicability, by excluding aeroplanes that have embodied Airbus mod 40161 in production.

You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9108.

Related Service Information Under 1 CFR Part 51

Airbus has issued Alert Operators Transmission A25L009–16, dated July 7, 2016. The service information describes procedures for the identifying the part number and serial number of door 3, Type 1, escape slides and replacing the escape slides. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are issuing this AD because we evaluated all pertinent information and determined the unsafe condition exists and is likely to exist or develop on other products of these same type designs.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because failure of an aspirator to inflate a door 3, Type 1, escape slide could prevent deployment of the escape slide during an emergency, possibly resulting in reduced evacuation capacity from the airplane and consequent injury to occupants. Therefore, we determined that notice and opportunity for public comment before issuing this AD are impracticable and that good cause exists for making this amendment effective in fewer than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–9108; Directorate Identifier 2016–NM–133–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this AD.

Costs of Compliance

We estimate that this AD affects 104 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	1 work-hour × $85 per hour = $85	$0	$85	$8,840

We estimate the following costs to do any necessary replacement that will be required based on the results of the inspection. We have no way of determining the number of airplanes that might need this replacement:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	2 work-hours × $85 per hour = $170	$45,000	$45,170

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2016–19–06 Airbus: Amendment 39–18655; Docket No. FAA–2016–9108; Directorate Identifier 2016–NM–133–AD.

(a) Effective Date

This AD becomes effective October 3, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the Airbus airplanes, certificated in any category, identified in paragraphs (c)(1) through (c)(4) of this AD, all manufacturer serial numbers, except those that have embodied Airbus Modification 40161 in production.

(1) Airbus Model A330–201, –202, –203, –223, and –243 airplanes.

(2) Airbus Model A330–301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes.

(3) Airbus Model A340–211, –212, and –213 airplanes.

(4) Airbus Model A340–311, –312, and –313 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/Furnishings.

(e) Reason

This AD was prompted by a report indicating that the aspirator on certain door 3, Type 1, escape slides might have been damaged because of incorrect packing during overhaul. We are issuing this AD to detect and correct damaged aspirators on door 3, Type 1, escape slides. Failure of an aspirator to inflate a door 3, Type 1, escape slide could prevent deployment of the escape slide during an emergency, possibly resulting in reduced evacuation capacity from the airplane and consequent injury to occupants.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspection To Determine Part Number and Serial Number

Within 30 days after the effective date of this AD: Do an inspection to determine the part number and serial number of the door 3, Type 1, escape slides on the left and right sides of the airplane, in accordance with the instructions of Airbus Alert Operators Transmission (AOT) A25L009–16, dated July 7, 2016. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number and serial number of the door 3, Type 1, escape slides can be conclusively determined from that review.

Note 1 to paragraph (g) of this AD: Airbus AOT A25L009–16, dated July 7, 2016, lists the corresponding airplane manufacturer serial numbers on which the affected slides (specified in table 1 to paragraphs (g), (i), and (j) of this AD) were re-installed after the last maintenance. That list of airplane manufacturer serial numbers is for information only because a potentially affected slide might have been removed from an airplane and later re-installed on another airplane.

TABLE 1 TO PARAGRAPHS (g), (i), AND (j) OF THIS AD—AFFECTED SLIDES

Slide part No.	Slide serial No.
7A1509–027	AD0918, AD0975, AD0979, AD1111, and AD1155.
7A1509–037	AD0488, AD0759, AD0942, AD0960, AD1025, AD1033, AD1034, AD1080, and AD1184.
7A1509–123	AD1231, AD1232, AD1450, AD1565, AD1730, AD1737, AD1805, AD1822, and AD1860.
7A1509–125	AD1769, AD1780, AD1781, AD1816, AD1834, AD1841, AD1862, AD1869, AD2066, AD2103, AD2104, AD2178, AD2223, AD2263, AD2279, AD2301, AD2407, AD2409, and AD2497.

(h) Corrective Action

If, during the inspection required by paragraph (g) of this AD, any door 3, Type 1, escape slide having a part number and a serial number identified in table 1 to paragraphs (g), (i), and (j) of this AD is found: At the applicable compliance time specified in paragraph (h)(1) or paragraph (h)(2) of this AD, replace each affected door 3, Type 1, escape slide with a serviceable escape slide, in accordance with the instructions of Airbus Alert Operators Transmission A25L009–16, dated July 7, 2016.

(1) For affected slides on both the left and right sides of the airplane: Within 30 days after the effective date of this AD, after identification as required by paragraph (g) of this AD, replace at least one slide; and, within 10 months or 4,100 flight hours, whichever occurs first after the effective date of this AD, replace the second slide.

(2) For one affected slide on either the left or right side of the airplane: Within 10 months or 4,100 flight hours, whichever occurs first after the effective date of this AD, replace the slide.

(i) Serviceable Escape Slide

For the purpose of this AD, a serviceable escape slide is a brand new escape slide or one that has a part number and serial number identified in table 1 to paragraphs (g), (i) and (j) of this AD and was overhauled after May 1, 2016.

(j) Parts Installation Limitation

As of the effective date of this AD, an affected slide having a part number and serial number identified in table 1 to paragraphs (g), (i), and (j) of this AD may be installed on any airplane at the door 3, Type 1, position, provided it can be positively determined that the slide was overhauled after May 1, 2016.

(k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1138; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(l) Related Information

Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2016–0137R1, dated July 21, 2016, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9108.

(m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Airbus Alert Operators Transmission A25L009–16, dated July 7, 2016.

(ii) Reserved.

(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *airworthiness.A330-A340@airbus.com;* Internet *http://www.airbus.com*.

(4) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For

information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on September 6, 2016.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–22178 Filed 9–15–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF STATE

22 CFR Part 42

[Public Notice: 9700]

RIN 1400–AD98

Visas: Diversity Immigrants

AGENCY: State Department.

ACTION: Final rule.

SUMMARY: This final rule is promulgated to clarify that photographs submitted as part of a diversity visa lottery entry package must have been taken no more than six months before the date the entry is made and prohibit applicants from wearing eyeglasses in photographs.

DATES: This rule is effective on October 17, 2016.

FOR FURTHER INFORMATION CONTACT: Andrea Lage, Legislation and Regulations Division, Visa Services, Bureau of Consular Affairs, Department of State, 600 19th St. NW., Washington, DC 20006, (202) 485–7585.

SUPPLEMENTARY INFORMATION:

What changes are in the amended rule?

The Diversity Immigrant Visa Program is administered annually by the Department of State (“Department”). Section 203(c) of the Immigration and Nationality Act (INA), 8 U.S.C. 1153(c), provides for a class of immigrants known as “diversity immigrants” from countries with historically low rates of immigration to the United States. From millions of applicants, certain individuals are selected through a randomized computer drawing (“selectees”) for consideration for one of the 50,000 available diversity visa numbers. These selectees are then given the opportunity to apply for a diversity immigrant visa or if present in the United States to apply for adjustment of status. To qualify for a visa, these “selectees” must meet certain requirements provided for at INA 203(c), 8 U.S.C. 1153(c), and 22 CFR 42.33.

Previously, 22 CFR 42.33(b)(2) required that photographs submitted with the diversity visa petition to be “recent.” 22 CFR 42.33(b)(2)(vii) only prohibited the wearing of sunglasses and other paraphernalia in photographs. The Department is amending the rule by adding a new subparagraph at § 42.33(b)(2)(iv) to require that the photograph be taken no more than six months prior to the date of the submission, and amending the photograph requirement to prohibit eyeglasses. The Department is also making a minor change by replacing “electronic entry form” with “petition” in the opening sentence of § 42.33(b)(2) to be consistent with the other parts of § 42.33(b).

Why is the Department promulgating this rule?

The Department receives unauthorized entries for the diversity visa lottery each year, including entries submitted by criminal enterprises. Requiring a new photograph be submitted each year reduces the ability for a third party to submit entries without an applicant’s knowledge. The added specificity also will support the Department’s practice of automatically disqualifying any applications for which a duplicate photograph was submitted, which also reduces the possibility of fraud, including fraud committed by criminal enterprises.

Regulatory Findings

Administrative Procedure Act

This regulation is exempt from the Administrative Procedure Act (APA) as it involves a foreign affairs function of the United States and, therefore, in accordance with 5 U.S.C. 553(a)(1), is exempt from the requirements of 5 U.S.C. 553. Since this rulemaking is exempt from section 553, the provisions of 5 U.S.C. 553(d) do not apply, and this rulemaking is effective immediately.

Regulatory Flexibility Act/Executive Order 13272: Small Business

Because this final rule is exempt from notice-and-comment rulemaking under 5 U.S.C. 553, it is exempt from the Regulatory Flexibility Act (5 U.S.C. 603 and 604). Nonetheless, consistent with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Department certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (codified at 2 U.S.C. 1532) generally requires agencies to prepare a statement before proposing any rule that may result in an annual expenditure of $100 million or more by State, local, or tribal governments, or by the private sector. This rule will not result in any such expenditure, nor will it significantly or uniquely affect small governments.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by 5 U.S.C. 804. The Department is aware of no monetary effect on the U.S. economy that will result from this rulemaking.

Executive Orders 12866 and 13563

The Department has reviewed this rule to ensure its consistency with the regulatory philosophy and principles set forth in Executive Order 12866, and has determined that the benefits of this regulation outweigh any cost. The Department has considered this rule in light of Executive Order 13563 and affirms that this regulation is consistent with the guidance therein. The Department does not consider this rule to be a significant rulemaking action.

Executive Orders 12372 and 13132: Federalism

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. The rule will not have federalism implications warranting the application of Executive Orders 12372 and 13132.

Executive Order 12988: Civil Justice Reform

The Department has reviewed the regulation in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not pre-empt tribal law. Accordingly, the requirements of Section 5 of Executive Order 13175 do not apply to this rulemaking.

Paperwork Reduction Act

This rule does not impose any new information collection requirements under the provisions of the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 42

Immigration, Passports and visas.

For the reasons stated in the preamble, the Department amends 22 CFR part 42 as follows:

PART 42—VISAS: DOCUMENTATION OF IMMIGRANTS UNDER THE IMMIGRATION AND NATIONALITY ACT, AS AMENDED

■ 1. The authority citation for part 42 is revised to read as follows:

Authority: 22 U.S.C. 2651a; 8 U.S.C. 1104; Pub. L. 105–277, 112 Stat. 2681–795 through 2681–801; 8 U.S.C. 1185 note (section 7209 of Pub. L. 108–458, as amended by section 546 of Pub. L. 109–295).

■ 2. Amend § 42.33 by:

■ a. Revising the introductory text of paragraph (b)(2);

■ b. Redesignating paragraphs (b)(2)(iv) through (viii) as paragraphs (b)(2)(v) through (ix), and adding a new paragraph (b)(2)(iv); and

■ c. Revising redesignated paragraph (b)(2)(viii).

The revisions and addition read as follows:

§ 42.33 Diversity immigrants.

* * * * *

(b) * * *

(2) *Requirements for photographs.* The petition will also require inclusion of a photograph of the petitioner and of his or her spouse and all unmarried children under the age of 21 years. The photographs must meet the following specifications:

* * * * *

(iv) The image must have been taken no more than six months prior to the date of the petition submission.

* * * * *

(viii) The person in the photograph must not wear eyeglasses, sunglasses, or other paraphernalia that obstruct the view of the face.

* * * * *

Michele Thoren Bond,

Assistant Secretary for Consular Affairs, Department of State.

[FR Doc. 2016–22365 Filed 9–15–16; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD–2015–HA–0109]

RIN 0720–AB65

TRICARE; Mental Health and Substance Use Disorder Treatment

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Final rule; technical amendment.

SUMMARY: On September 2, 2016, the Department of Defense published a final rule (81 FR 61068–61098) titled TRICARE; Mental Health and Substance Use Disorder Treatment. DoD is making a technical amendment due to the discovery of two errors. We noted in the preamble of the final rule that we had removed the requirements regarding capacity (30 percent) and length of time licensed and at full operational status (6 months) for substance use disorder rehabilitation facilities (SUDRFs). However, we did not remove the necessary sentence in the regulatory text.

In a response to a public comment in the preamble of the final rule, we said that TRICARE will require opioid treatment programs (OTPs) to be licensed and operate in substantial compliance with state and federal regulations. However, we did not make the necessary change in the regulatory text. This technical amendment corrects those errors.

DATES: This rule is effective on October 3, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Patricia Toppings, 571–372–0485.

SUPPLEMENTARY INFORMATION: This technical amendment amends 32 CFR part 199 to read as set forth in the amendatory language in this final rule.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Mental health, Mental health parity, Military personnel, Substance use disorder treatment.

Accordingly, 32 CFR part 199 is amended as follows:

PART 199—CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)

■ 1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

■ 2. Amend § 199.6(b)(4)(xiv)(B) to remove "In addition, such a Participation Agreement may not be signed until an SUDRF has been licensed and operational for at least six months."

■ 3. Revise § 199.6(b)(4)(xix)(A)(*2*)(*ii*) to read as follows:

§ 199.6 TRICARE-authorized providers.

(b) * * *

(4) * * *

(xix) * * *

(A) * * *

(*2*) * * *

(*ii*) To qualify as a TRICARE authorized provider, OTPs are required to be licensed and operate in substantial compliance with state and federal regulations.

* * * * *

Dated: September 13, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–22363 Filed 9–15–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2016–0864]

RIN 1625–AA08

Special Local Regulation; Ohio River, Owensboro, KY

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a special local regulation on the Ohio River from mile 755.0 to mile 759.0 in Owensboro, KY on September 30, 2016 through October 2, 2016. This special regulation is necessary to provide for the safety of life on these navigable waters near Owensboro, KY, during the Owensboro Air Show. This rulemaking prohibits transit into, through, and within the regulated area unless authorized by the Captain of the Port Ohio Valley or a designated representative.

DATES: This rule is effective from 12 p.m. on September 30, 2016 through 4:30 p.m. on October 2, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov*, type *USCG–2016–0864* in the "SEARCH" box and click "SEARCH." Click on Open Docket

Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer James Robinson, Sector Ohio Valley, U.S. Coast Guard; telephone 502–779–5347, email *James.C.Robinson@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the event is being held outside of the date and location currently contemplated in the publication. It is impracticable to publish an NPRM because we must establish this special local regulation by September 30, 2016.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. Delaying this rule would be unnecessary as this event is a recurring event and mariners familiar with this location on the Ohio River are aware that in mid to late September, a weekend event air show takes place. This year, the event will occur 01 weekend later than is currently published in the **Federal Register**. Furthermore, delaying this rule would be contrary to public interest of ensuring the safety of spectators and vessels during the event and immediate action is necessary to prevent possible loss of life and property. Broadcast Notices to Mariners (BNM) and information sharing with the waterway users will update mariners of the restrictions, requirements and enforcement times during this temporary situation.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1233. The Captain of the Port Ohio Valley (COTP) has determined that potential hazards associated with the air show starting September 30, 2016 will be a safety concern for anyone within the regulated area. The purpose of this rule is to ensure safety of life on the navigable waters in the temporary regulated area before, during, and after the Owensboro Air Show.

IV. Discussion of the Rule

The Coast Guard will establish a special local regulation from September 30, 2016 through October 2, 2016. The special local regulation will cover all navigable waters from mile 755.0 to 759.0 on the Ohio River in the vicinity of Owensboro, KY. Transit into and through this area is prohibited from 12 p.m. to 3:30 p.m. on September 30, 2016, 12 p.m. to 4:30 p.m. on October 01, 2016, and 12 p.m. to 4:30 p.m. on October 2, 2016. The duration of the regulation is intended to protect participants, spectators, and other persons and vessels before, during, and after the scheduled air show. No vessel or person will be permitted to enter the special local regulation without obtaining permission from the COTP or a designated representative. Deviation requests will be considered and reviewed on a case-by-case basis. The COTP Ohio Valley may be contacted by telephone at 1–800–253–7475 or can be reached by VHF–FM channel 16. Public notifications will be made to the local maritime community prior to the event through the Local Notice to Mariners, and Broadcast Notice to Mariners.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, duration, and time-of-year of the special local regulation. The temporary special local regulation will only be in effect for less than five hours each day. The Coast Guard expects minimum adverse impact to mariners from the special local regulation's activation as the event has been advertised to the public. Also, mariners may request authorization from the COTP Ohio Valley or the designated representatives to transit the regulated area.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the regulated area may be small entities, for the reasons stated in section V. above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for Federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, KY the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a special local regulation lasting less than five hours a day that will prohibit entry on all waters of the Ohio River, surface to bottom, extending from mile 755.0 to 759.0. It is categorically excluded from further review under paragraph 34(h) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES.**

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Add § 100.35T08–0864 to read as follows:

§ 100.35T08–0864 Special Local Regulation; Ohio River, Owensboro, KY.

(a) *Regulated area.* All waters of the Ohio River beginning at mile marker 755.0 and ending at mile marker 759.0 in Owensboro, KY.

(b) *Period of enforcement.* This rule will be enforceable from 12 p.m. to 3:30 p.m. on September 30, 2016, 12 p.m. to 4:30 p.m. on October 1, 2016, and 12 p.m. to 4:30 p.m. on October 2, 2016.

(c) *Special local regulations.* (1) Persons or vessels desiring to enter into or passage through the zone must request permission from the COTP Ohio Valley or a designated representative. They may be contacted on VHF–FM radio channel 16 or phone at 1–800–253–7465.

(2) The Coast Guard will patrol the regulated area under the direction of a designated Coast Guard Patrol Commander. The Patrol Commander may be contacted via VHF–FM radio channel 16 or by phone at 502–587–8633.

(3) The Patrol Commander may terminate the event or the operation of any vessel at any time it is deemed necessary for the protection of life or property.

(d) *Informational broadcasts.* The COTP Ohio Valley or a designated representative will inform the public through broadcast notices to mariners of the enforcement period for the regulated area as well as any changes in the planned schedule.

Dated: September 12, 2016.

M.B. Zamperini,

Captain, U.S. Coast Guard, Captain of the Port Ohio Valley.

[FR Doc. 2016–22281 Filed 9–15–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2016–0714]

Special Local Regulations; Ironman 70.3 Augusta Triathlon, Savannah River

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Ironman 70.3 Augusta Triathlon, Savannah River, Special Local Regulation from 7 a.m. through 11 a.m. on September 25, 2016. This action is necessary to ensure safety of life on navigable waterways of the United States during this event. During the enforcement period, and in accordance with previously issued special local regulations, vessels may not enter, transit through, anchor in, remain within the designated area unless authorized by the Captain of the Port (COTP) Savannah or a designated representative.

DATES: The regulation in 33 CFR 100.701, Table to § 100.71, Item (f)3 will be enforced from 7 a.m. through 11 a.m. on September 25, 2016.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email MST1 Cliffton Hendry, Marine Safety Unit Savannah Office of Waterways Management, Coast Guard; telephone 912–652–4353, extension 243, or email *Cliffton.R.Hendry@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation for the Ironman 70.3 Augusta Triathlon, Savannah River, in 33 CFR 100.701 from 7 a.m. through 11 a.m. on September 25, 2016.

This action is to provide enforcement action of the regulated area that will encompass portions of the navigable waterways. The location of the regulated area for this 1.2 mile long swim course, as stated in the latitude/longitude figures in 33 CFR 100.701, Table to § 100.701, Item (f)3, begins at the 5th Street Marina in Augusta, GA, and proceeds downriver to The Boathouse, 101 Riverfront Drive, Augusta, GA. Under the provisions of 33 CFR 100.701, all persons and vessels are prohibited from entering the regulated areas unless permission to enter has been granted by the COTP or designated representatives.

This notice of enforcement is issued under authority of 33 CFR 100.701 and 5 U.S.C. 552 (a). The Coast Guard will provide notice of the regulated areas by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives. If the COTP Savannah determines that the regulated area need not be enforced for the full duration stated in this publication, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: September 1, 2016.

A.M. Beach,

Commander, U.S. Coast Guard, Captain of the Port, Savannah.

[FR Doc. 2016–22356 Filed 9–15–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2016–0717]

RIN 1625–AA08

Special Local Regulation; Ohio River, Madison, IN

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a special local regulation for all waters of the Ohio River, surface to bottom, extending from Ohio River mile 557.5 to 558.5 in Madison, IN on September 17 and September 18, 2016. This action is necessary to provide for the safety of life on these navigable waters near Madison, IN during the high-speed boat race on September 17 and September 18, 2016. This regulation prohibits persons and vessels from being in the regulated area unless authorized by the Captain of the Port Ohio Valley or a designated representative.

DATES: This rule is effective from 8 a.m. on September 17, 2016 to 6 p.m. September 18, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type [USCG–2016–0717] in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Joshua Herriott, Sector Ohio Valley, U.S. Coast Guard; telephone 502–779–5343, email *Joshua.R.Herriott@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

On February 03, 2016, the "5 to the 5" Vintage Hydros Organization notified the Coast Guard that it will be sponsoring a high-speed boat race from 8:00 a.m. to 6:00 p.m. on September 17 and September 18, 2016. The race will take place at Ohio River mile 557.5 to 558.5 in the vicinity of Madison, IN. The Captain of the Port Ohio Valley (COTP) has determined that potential hazards associated with the high-speed regatta would be a safety concern for anyone within in the proposed regulated area.

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because there is not time to complete the NPRM process due to unforeseen administrative delays. This event has been advertised to the local community and waterway users and it would be impracticable solicit public comment for this event because it must be in place on September 17 and September 18, 2016.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. This rule is necessary for the safety of life during high-speed boat races on this section of navigable waters. It would be impracticable to delay this rule to provide a full 30 days notice because the event is scheduled and has been advertised to the local community to take place on September 17 and September 18, 2016.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1233. The Captain of the Port Ohio Valley (COTP) has deemed the potential hazards associated with the high-speed boat races to occur September 17 and September 18, 2016 will be a safety concern for anyone within the regulated area. The purpose of this rulemaking is to ensure the safety of vessels and spectators within the regulated area before, during, and after the scheduled event.

IV. Discussion of the Rule

As noted above, the Coast Guard will establish a special local regulation from 8:00 a.m. to 6:00 p.m. on September 17 and September 18, 2016. The special local regulation will cover all navigable waters from mile 557.5 to 558.5 on the Ohio River in the vicinity of Madison, IN. The duration of the regulated area is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled event. No vessel or person will be permitted to enter the special local regulation without obtaining permission from the COTP or a designated representative. Deviation requests will be considered and reviewed on a case-by-case basis. The COTP Ohio Valley may be contacted by telephone at 1–800–253–7475 or can be reached by VHF–FM channel 16. Public notifications will be made to the local maritime community prior to the event through the Local Notice to Mariners, and Broadcast Notice to Mariners.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders, and we discuss the First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, duration, and time-of-day of the regulated area. Vessel traffic will be able to safely transit through the affected area before and after the scheduled event. Moreover, the Coast Guard will issue Broadcast Notice to Mariners via VHF–FM marine channel 16 about the regulated area and the rule allows vessels to seek permission to enter the area.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the regulated area may be small entities, for the reasons stated in section V. above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for Federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental Federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for Federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, IN the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a special local regulation lasting from 8:00 a.m. to 6:00 p.m. on September 17 and September 18, 2016. It is categorically excluded from further review under paragraph 34(h) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Add § 100.35T08–0717 to read as follows:

§ 100.35T08–0717 Special Local Regulation; Ohio River, Mile 557.5 to 558.5, Madison, IN.

(a) *Location.* All waters of the Ohio River beginning at mile marker 557.5 and ending at mile marker 558.5 in Madison, IN.

(b) *Period of enforcement.* This rule will be enforceable from 8:00 a.m. to 6:00 p.m. on September 17 and September 18, 2016.

(c) *Regulations.* (1) In accordance with the general regulations in § 100.35, entry into this area is prohibited unless authorized by the Captain of the Port Ohio Valley or a designated representative.

(2) Persons or vessels desiring entry into or passage through the area must request permission from the Captain of the Port Ohio Valley or a designated representative. U.S. Coast Guard Sector

Ohio Valley may be contacted on VHF Channel 13 or 16, or at 1–800–253–7465.

Dated: September 12, 2016.

M.B. Zamperini,

Captain, U.S. Coast Guard, Captain of the Port Ohio Valley.

[FR Doc. 2016–22319 Filed 9–15–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0674]

Drawbridge Operation Regulation; South Branch of the Elizabeth River, Atlantic Intracoastal Waterway, Chesapeake, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Gilmerton (US13/460) Bridge across the South Branch of the Elizabeth River, mile 5.8, on the Atlantic Intracoastal Waterway, at Chesapeake, VA. This deviation is necessary to avoid bridge failure and perform emergency bridge repairs. This deviation allows the bridge to remain in the closed-to-navigation position.

DATES: This deviation is effective without actual notice from September 16, 2016 through 5 a.m. on September 19, 2016. For the purposes of enforcement, actual notice will be used from September 13, 2016 at 9 a.m., until September 16, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–0674] is available at *http://www.regulations.gov.* Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Hal R. Pitts, Bridge Administration Branch Fifth District, Coast Guard, telephone 757–398–6222, email *Hal.R.Pitts@uscg.mil.*

SUPPLEMENTARY INFORMATION: The City of Chesapeake, that owns and operates the Gilmerton (US13/460) Bridge, across the South Branch of the Elizabeth River, mile 5.8, on the Atlantic Intracoastal Waterway, at Chesapeake, VA, has requested a temporary deviation from the current operating regulations to avoid bridge failure and perform emergency repairs to the bridge due to failure of operating mechanism components, requiring non-standard manual operation of the bridge until repair is completed. The bridge is a vertical lift draw bridge and has a vertical clearance in the closed position of 36 feet above mean high water. The vertical clearance of the bridge in the open-to-navigation position of 136 feet above mean high water will be reduced to approximately 110 feet above mean high water from 9 p.m. on September 16, 2016, through 5 a.m. on September 19, 2016.

The current operating schedule is set out in 33 CFR 117.997(c). Under this temporary deviation, the bridge will remain in the closed-to-navigation position, except for scheduled openings at 9 a.m., noon, 3 p.m. and 7 p.m., Monday through Friday; and 9 a.m. and 3 p.m. on Saturday and Sunday. The scheduled openings at 9 a.m. and 3 p.m. on Saturday and Sunday, September 17, 2016, and September 18, 2016; and emergency openings from 9 p.m. on September 16, 2016, through 5 a.m. on September 19, 2016, will provide a reduced vertical clearance of approximately 110 feet above mean high water.

The South Branch of the Elizabeth River is used by a variety of vessels including U.S. government and public vessels, commercial vessels, tug and barge traffic, and recreational vessels. The Coast Guard has carefully coordinated the restrictions with waterway users in publishing this temporary deviation.

Vessels able to safely pass through the bridge in the closed position may do so at any time. On Saturday and Sunday, September 17, 2016, and September 18, 2016, vessels able to safely pass through the bridge in the closed position should contact the bridge tender to ensure safe passage through the bridge. There is no immediate alternate route for vessels unable to pass through the bridge in the closed position. The bridge will open on signal for emergency vessels, if at least one hour notice is given. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transit to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: September 13, 2016.

Hal R. Pitts,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2016–22320 Filed 9–15–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0866]

Drawbridge Operation Regulation; James River, Isle of Wight and Newport News, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the James River Bridge (US17) across the James River, mile 5.0, at Isle of Wight and Newport News, VA. The deviation is necessary to perform bridge maintenance and repairs. This deviation allows the bridge to remain in the closed-to-navigation position.

DATES: This deviation is effective from 5 a.m. on September 19, 2016, to 7 p.m. on October 16, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–0866] is available at *http://www.regulations.gov.* Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Hal R. Pitts, Bridge Administration Branch Fifth District, Coast Guard, telephone 757–398–6222, email *Hal.R.Pitts@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Virginia Department of Transportation, that owns and operates the James River Bridge (US17), across the James River, mile 5.0, at Isle of Wight and Newport News, VA, has requested a temporary deviation from the current operating regulations to perform repairs to the aerial electrical cable connecting the north tower to the south tower. The bridge is a vertical lift draw bridge and has a vertical clearance in the closed position of 60 feet above mean high water.

The current operating schedule is open on signal as set out in 33 CFR 117.5. Under this temporary deviation, the bridge will remain in the closed-to-navigation position from 5 a.m. to 7 p.m. from September 19, 2016, through September 30, 2016; with alternate dates from October 1, 2016, through October 16, 2016. During this temporary deviation, the bridge will operate per 33 CFR 117.5 from 7 p.m. to 5 a.m.

The James River is used by a variety of vessels including deep draft ocean-going vessels, U. S. government vessels, small commercial vessels, recreational vessels and tug and barge traffic. The Coast Guard has carefully coordinated the restrictions with waterway users.

During closure periods a 55-foot by 150-foot crane barge will be positioned alongside the bridge at various locations within the main navigation span of the bridge with the centerline of the barge perpendicular to the bridge. Vessels able to safely pass through the bridge in the closed position with the crane barge positioned alongside the bridge may do so at anytime. Vessels planning to transit through the bridge in the closed position with the crane barge positioned alongside the bridge shall contact the bridge tender to request information concerning the position of the crane barge to ensure safe passage.

Vessels able to safely pass through the bridge in the closed position that require the crane barge to clear the main navigation span of the bridge, may do so at noon, daily, if at least two hours advance notice is given to the bridge tender. The bridge will open on signal for vessels that require an opening of the bridge and are unable to transit through the bridge during non-closure times due to draft and/or daylight restrictions, if notice is provided by 5 p.m. the day before the required bridge opening. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transit to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: September 13, 2016.

Hal R. Pitts,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2016–22300 Filed 9–15–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2016–0304; FRL–9952–47–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Control of Volatile Organic Compounds Emissions From Fiberglass Boat Manufacturing Materials; Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to the receipt of a comment, the Environmental Protection Agency (EPA) is withdrawing the direct final rule published on August 1, 2016, to approve the State of Maryland's adoption of the requirements in EPA's control technique guidelines (CTG) for fiberglass boat manufacturing materials.

DATES: The direct final rule published at 81 FR 50336 on August 1, 2016, is withdrawn effective September 16, 2016.

FOR FURTHER INFORMATION CONTACT: Gavin Huang, (215) 814–2042, or by email at *huang.gavin@epa.gov.*

SUPPLEMENTARY INFORMATION: In the direct final rule published on August 1, 2016 (81 FR 50336), we stated that if we received comment by August 31, 2016, the rule would be withdrawn and not take effect. EPA received a comment before the August 31, 2016 deadline. EPA will address the comment received in a subsequent final action based upon the proposed action also published on August 1, 2016 (81 FR 50427). EPA will not institute a second comment period on this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Ozone, Volatile organic compounds.

Dated: September 6, 2016.

Shawn M. Garvin,

Regional Administrator, Region III.

■ Accordingly, the direct final rule which published in the **Federal Register** on August 1, 2016, at 81 FR 50336 is withdrawn as of September 16, 2016.

[FR Doc. 2016–22225 Filed 9–15–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2016–0473; FRL–9952–30–Region 4]

Air Plan Approval; Alabama: Volatile Organic Compounds

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a portion of a revision to the Alabama State Implementation Plan (SIP) submitted by the Alabama Department of Environmental Management (ADEM) on May 8, 2013. The revision modifies the definition of "volatile organic compounds" (VOC). Specifically, the revision adds one compound to the list of those excluded from the VOC definition on the basis that this compound makes a negligible contribution to tropospheric ozone formation. This action is being taken pursuant to the Clean Air Act (CAA or Act).

DATES: This direct final rule is effective November 15, 2016 without further notice, unless EPA receives adverse comment by October 17, 2016. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2016–0473 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Sean Lakeman, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Mr. Lakeman can be reached by phone at (404) 562–9043 or via electronic mail at *lakeman.sean@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Tropospheric ozone, commonly known as smog, occurs when VOC and nitrogen oxides (NO_X) react in the atmosphere in the presence of sunlight. Because of the harmful health effects of ozone, EPA and state governments limit the amount of VOC and NO_X that can be released into the atmosphere. VOC are those compounds of carbon (excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate) that form ozone through atmospheric photochemical reactions. Compounds of carbon (or organic compounds) have different levels of reactivity; they do not react at the same speed or do not form ozone to the same extent.

Section 302(s) of the CAA specifies that EPA has the authority to define the meaning of "VOC," and hence what compounds shall be treated as VOC for regulatory purposes. It has been EPA's policy that compounds of carbon with negligible reactivity need not be regulated to reduce ozone and should be excluded from the regulatory definition of VOC. *See* 42 FR 35314 (July 8, 1977), 70 FR 54046 (September 13, 2005). EPA determines whether a given carbon compound has "negligible" reactivity by comparing the compound's reactivity to the reactivity of ethane. EPA lists these compounds in its regulations at 40 CFR 51.100(s) and excludes them from the definition of VOC. The chemicals on this list are often called "negligibly reactive." EPA may periodically revise the list of negligibly reactive compounds to add or delete compounds.

EPA issued a final rule approving the addition of trans-1,3,3,3-tetrafluropropene (also known as HFO-1234ze) to the list of those compounds excluded from the regulatory definition of VOC. *See* 77 FR 37610 (June 22, 2012). Alabama is updating its SIP to be consistent with that change to federal regulations.

II. Analysis of State's Submittal

On May 8, 2013, ADEM submitted a SIP revision[1] to EPA for review and approval. The revision modifies the definition of VOC found at Alabama Administrative Code section 335–3–1–.02(gggg). Specifically, the revision adds trans-1,3,3,3-tetrafluropropene (also known as HFO-1234ze) to the list of compounds excluded from the VOC definition on the basis that this compound makes a negligible contribution to tropospheric ozone formation.

This change is consistent with section 110 of the CAA and meets the regulatory requirements pertaining to SIPs. Pursuant to CAA section 110(l), the Administrator shall not approve a revision of a plan if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in CAA section 171), or any other applicable requirement of the Act. The revision to Rule 335–3–1–.02(gggg) is approvable under section 110(l) because it reflects changes to federal regulations based on findings that the aforementioned compound is negligibly reactive.

III. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of Alabama Regulation section 335–3–1–.02 "Definitions," effective November 24, 2015, which is the most up to date version of the definition of VOC.[2] Therefore, this material has been approved by EPA for inclusion in the SIP, has been incorporated by reference by EPA into that plan, is fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference by the Director of the Federal Register in the next update to the SIP compilation.[3] EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and/or at the EPA Region 4 Office (please contact the person identified in the "For Further Information Contact" section of this preamble for more information).

IV. Final Action

Pursuant to section 110 of the CAA, EPA is approving the revision to the Alabama SIP changing the VOC definition. EPA has evaluated Alabama's May 8, 2013, submittal and has determined that it meets the applicable requirements of the CAA and EPA regulations and is consistent with EPA policy.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective November 15, 2016 without further notice unless the Agency receives adverse comments by October 17, 2016.

If EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period. Parties interested in commenting should do so at this time. If no such comments are received, the public is advised that this rule will be effective on November 15, 2016 and no further action will be taken on the proposed rule.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);

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[1] EPA will consider the other changes included in Alabama's May 8, 2013, SIP submittal, which relate to permitting, greenhouse gases, and transportation conformity, in a future rulemaking.

[2] Although the effective date of the rule change made in Alabama's May 8, 2013, SIP revision is May 28, 2013, the most recent version of Alabama's Rule 335–3–1–.02(gggg) which is approved into the federally-approved SIP is November 24, 2015. *See* 81 FR 49899 (July 29, 2016). The November 24, 2015, version of Alabama's Rule 335–3–1–.02(gggg) captures the changes the State made to this rule, effective May 28, 2013.

[3] 62 FR 27968 (May 22, 1997).

- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 15, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of this **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: September 2, 2016.

V. Anne Heard,

Acting Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart B—Alabama

■ 2. Section 52.50(c) is amended by revising the entry for ''Section 335–3–1–.02'' to read as follows:

§ 52.50 Identification of plan.

* * * * *

(c) * * *

EPA APPROVED ALABAMA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
Chapter 335–3–1—General Provisions				
*	*	*	*	*
Section 335–3–1–.02	Definitions	11/24/2015	9/16/2016, [Insert **Federal Register** citation].	
*	*	*	*	*

* * * * *

[FR Doc. 2016–22221 Filed 9–15–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2015–0251; FRL–FRL–9952–28–Region 4]

Air Plan Approval; SC Infrastructure Requirements for the 2010 1-Hour NO_2 NAAQS

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve portions of the State Implementation Plan (SIP) submission, submitted by the State of South Carolina, through the South Carolina Department of Health and Environmental Control (SC DHEC) on April 30, 2014, to demonstrate that the State meets certain infrastructure requirements of the Clean Air Act (CAA or Act) for the 2010 1-hour nitrogen dioxide (NO_2) national ambient air quality standards (NAAQS). The CAA requires that each state adopt and submit a SIP for the implementation, maintenance and enforcement of each NAAQS promulgated by EPA, which is commonly referred to as an "infrastructure" SIP. SC DHEC certified that the South Carolina SIP contains provisions that ensure the 2010 NO_2 NAAQS are implemented, enforced, and maintained in South Carolina. EPA has determined that South Carolina's SIP satisfies certain required infrastructure elements for the 2010 NO_2 NAAQS.

DATES: This rule will be effective October 17, 2016.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2015–0251. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *i.e.*, Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Richard Wong, Air Regulatory Management Section, Air Planning and Implementation Branch, Pesticides and Toxics Management Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8726. Mr. Richard Wong can also be reached via electronic mail at *wong.richard@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Overview

On January 22, 2010, (published at 75 FR 6474, February 9, 2010), EPA promulgated a new 1-hour primary NAAQS for NO_2 at a level of 100 parts per billion, based on a 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum concentrations. Pursuant to section 110(a)(1) of the CAA, states are required to submit SIPs meeting the requirements of section 110(a)(2) within three years after promulgation of a new or revised NAAQS or within such shorter period as EPA may prescribe. Section 110(a)(2) requires states to address basic SIP elements such as requirements for monitoring, basic program requirements and legal authority that are designed to assure attainment and maintenance of the NAAQS. States were required to submit such SIPs for the 2010 NO_2 NAAQS to EPA no later than January 22, 2013.

In a proposed rulemaking published on June 27, 2016 (81 FR 41498), EPA proposed to approve South Carolina's 2010 1-hour NO_2 NAAQS infrastructure SIP submission submitted on April 30, 2014, with the exception of the PSD permitting requirements for major sources of sections 110(a)(2)(C), prong 3 of D(i), and (J) and the interstate transport requirements of section 110(a)(2)(D)(i)(I) and (II) (prongs 1, 2, and 4), for which EPA did not propose any action. On March 18, 2015 (80 FR 14019), EPA approved South Carolina's April 30, 2014, infrastructure SIP submission regarding the PSD permitting requirements for major sources of sections 110(a)(2)(C), prong 3 of D(i), and (J) for the 2010 1-hour NO_2 NAAQS. Therefore, EPA is not taking any action today pertaining to sections 110(a)(2)(C), prong 3 of D(i) and (J). On August 22, 2016 (81 FR 56512) EPA conditionally approved South Carolina's April 30, 2014, infrastructure SIP submission regarding prong 4 of D(i) for the 2010 1-hour NO_2 NAAQS. Therefore, EPA is not taking any action today pertaining to prong 4. With respect to the interstate transport requirements of section 110(a)(2)(D)(i)(I) (prongs 1 and 2), EPA does not yet have a submission before the Agency for action. The details of South Carolina's submission and the rationale for EPA's action are explained in the proposed rulemaking. Comments on the proposed rulemaking were due on or before July 28, 2016. EPA received no adverse comments on the proposed action.

II. Final Action

With the exception of the PSD permitting requirements for major sources of sections 110(a)(2)(C), prong 3 of D(i), and (J) and the interstate transport requirements of section 110(a)(2)(D)(i)(I) and (II) (prongs 1, 2, and 4), EPA is taking final action to approve South Carolina's infrastructure SIP submission for the 2010 1-hour NO_2 NAAQS. EPA is taking final action to approve portions of South Carolina's infrastructure SIP submission for the 2010 1-hour NO_2 NAAQS because it is consistent with section 110 of the CAA.

III. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this action for the state of South Carolina does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). The Catawba Indian Nation Reservation is located within the State of South Carolina. Pursuant to the Catawba Indian Claims Settlement Act, South Carolina statute 27–16–120, "all state and local environmental laws and regulations apply to the [Catawba Indian Nation] and Reservation and are fully enforceable by all relevant state and local agencies and authorities." However, EPA has determined that this rule does not have substantial direct effects on an Indian Tribe because this action is not approving any specific rule, but rather approving that South Carolina's already approved SIP meets certain CAA requirements. EPA notes this action will not impose substantial direct costs on Tribal governments or preempt Tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 15, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: September 2, 2016.

V. Anne Heard,

Acting Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42.U.S.C. 7401 *et seq.*

Subpart PP—South Carolina

■ 2. In § 52.2120, the table in paragraph (e) is amended by adding the entry "110(a)(1) and (2) Infrastructure Requirements for the 2010 1-hour NO_2 NAAQS" at the end of the table to read as follows:

§ 52.2120 Identification of plan.

* * * * *

(e) * * *

Provision	State effective date	EPA approval date	Explanation
* * *	*	* *	* *
110(a)(1) and (2) Infrastructure Requirements for the 2010 1-hour NO_2 NAAQS.	04/30/2014	09/16/2016, [Insert **Federal Register** citation].	With the exception of sections 110(a)(2)(C), prong 3 of D(i), and (J) and sections 110(a)(2)(D)(i)(I) and (II) (prongs 1, 2, and 4).

[FR Doc. 2016–22239 Filed 9–15–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2014–0751; FRL–9952–33–Region 4]

Air Plan Approval/Disapproval; MS Infrastructure Requirements for the 2010 NO_2 NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve in part, and disapprove in part, portions of the State Implementation Plan (SIP) submission, submitted by the State of Mississippi, through the Mississippi Department of Environmental Quality (MDEQ) on February 28, 2013, to demonstrate that the State meets the infrastructure requirements of the Clean Air Act (CAA or Act) for the 2010 1-hour nitrogen dioxide (NO_2) national ambient air quality standards (NAAQS). The CAA requires that each state adopt and submit a SIP for the implementation, maintenance and enforcement of each NAAQS promulgated by EPA, which is commonly referred to as an "infrastructure" SIP. The MDEQ certified that the Mississippi SIP contains provisions that ensure the 2010 NO_2 NAAQS are implemented, enforced, and maintained in Mississippi. With the exception of the state board majority requirements respecting significant portion of income, for which EPA is disapproving, EPA has determined portions of Mississippi's SIP submission, provided to EPA on

February 28, 2013, satisfies certain required infrastructure elements for the 2010 1-hour NO_2 NAAQS.

DATES: This rule will be effective October 17, 2016.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2014–0751. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Richard Wong, Air Regulatory Management Section, Air Planning and Implementation Branch, Pesticides and Toxics Management Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8726. Mr. Richard Wong can also be reached via electronic mail at *wong.richard@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Overview

On January 22, 2010, (published at 75 FR 6474, February 9, 2010), EPA promulgated a new 1-hour primary NAAQS for NO_2 at a level of 100 parts per billion (ppb), based on a 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum concentrations. Pursuant to section 110(a)(1) of the CAA, states are required to submit SIPs meeting the requirements of section 110(a)(2) within three years after promulgation of a new or revised NAAQS or within such shorter period as EPA may prescribe. Section 110(a)(2) requires states to address basic SIP elements such as requirements for monitoring, basic program requirements and legal authority that are designed to assure attainment and maintenance of the NAAQS. States were required to submit such SIPs for the 2010 NO_2 NAAQS to EPA no later than January 22, 2013.

In a proposed rulemaking published on May 24, 2016, EPA proposed to approve Mississippi's 2010 1-hour NO_2 NAAQS infrastructure SIP submission submitted on February 28, 2013, with the exception of the preconstruction PSD permitting requirements for major sources of sections 110(a)(2)(C), prong 3 of (D)(i), and (J), the interstate transport requirements of section 110(a)(2)(D)(i)(I) and (II) (prongs 1, 2, and 4), and the state board majority requirements respecting significant portion of income of 110(a)(2)(E)(ii). On March 18, 2015 (80 FR 14019), EPA approved Mississippi's February 28, 2013, infrastructure SIP submission regarding the PSD permitting requirements for major sources of sections 110(a)(2)(C), prong 3 of D(i), and (J) for the 2010 1-hour NO_2 NAAQS. Therefore, EPA is not taking any action today pertaining to sections 110(a)(2)(C), prong 3 of D(i), and (J). Additionally, on May 25, 2016, EPA took final action on prong 4 of D(i) element of Mississippi's February 28, 2013, SIP submission for the 2010 1-hour NO_2 NAAQS and is not acting on this prong in this action. *See* 81 FR 33139. With respect to the interstate transport requirements of section 110(a)(2)(D)(i)(I) (prongs 1 and 2), Mississippi provided a separate submission on July 14, 2016. EPA is considering action on Mississippi's submission related to 110(a)(2)(D)(i)(I) (prongs 1 and 2) through a separate action. The details of Mississippi's submission and the rationale for EPA's actions for this final rulemaking are explained in the May 24, 2016, proposed rulemaking. Comments on the proposed rulemaking were due on or before June 23, 2016. EPA received no adverse comments on the proposed action.

II. Final Action

With regard to the state board majority requirements respecting significant portion of income, EPA is finalizing a disapproval of Mississippi's February 28, 2013, infrastructure submission. Under section 179(a) of the CAA, final disapproval of a submittal that addresses a requirement of a CAA Part D Plan, or is required in response to a finding of substantial inadequacy as described in CAA section 110(k)(5) (SIP call), starts a sanctions clock. The portion of the submittal being disapproved in this notice (the portion addressing certain provisions of section 110(a)(2)(E)(ii)) was not submitted to meet requirements for Part D or a SIP call, and therefore, no sanctions will be triggered. However, this final action will trigger the requirement under section 110(c) that EPA promulgate a Federal Implementation Plan (FIP) no later than two years from the date of the disapproval unless the State corrects the deficiency, and EPA approves the plan or plan revision before EPA promulgates such FIP. With the exceptions described above, EPA is taking final action to approve Mississippi's infrastructure SIP submission for the 2010 1-hour NO_2 NAAQS because these portions of the submission are consistent with section 110 of the CAA.

III. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because

application of those requirements would be inconsistent with the CAA; and

- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 15, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: September 2, 2016.

V. Anne Heard,

Acting Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42.U.S.C. 7401 *et seq.*

Subpart Z—Mississippi

■ 2. Section 52.1270(e), is amended by adding an entry for "110(a)(1) and (2) Infrastructure Requirements for the 2010 1-hour NO_2 National Ambient Air Quality Standard" at the end of the table to read as follows:

§ 52.1270 Identification of plan.

* * * * *

(e) * * *

EPA APPROVED MISSISSIPPI NON-REGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date	Explanation
*	*	*	*	* * *
110(a)(1) and (2) Infrastructure Requirements for the 2010 1-hour NO_2 National Ambient Air Quality Standard.	Mississippi	02/28/2013	09/16/2016, [Insert **Federal Register** citation].	With the exception of sections: 110(a)(2)(C) and (J) concerning PSD permitting requirements; 110(a)(2)(D)(i)(I) and (II) (prongs 1 through 4) concerning interstate transport requirements and the state board majority requirements respecting significant portion of income of section 110(a)(2)(E)(ii).

■ 3. Section 52.1272 is amended by adding a paragraph (d) to read as follows:

§ 52.1272 Approval status.

* * * * *

(d) *Disapproval.* Submittal from the State of Mississippi, through the Mississippi Department of Environmental Quality (MDEQ) on February 28, 2013, to address the Clean Air Act section 110(a)(2)(E)(ii) for the 2010 1-hour nitrogen dioxide (NO_2) National Ambient Air Quality Standards (NAAQS) concerning state board majority requirements respecting significant portion of income of section 128(a)(1). EPA is disapproving MDEQ's submittal with respect to section 110(a)(2)(E)(ii) because a majority of board members may still derive a significant portion of income from persons subject to permits or enforcement orders issued by the Mississippi Boards, and therefore, its current SIP does not meet the section 128(a)(1) majority requirements respecting significant portion of income for the 2010 1-hour NO_2 NAAQS.

[FR Doc. 2016–22226 Filed 9–15–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0742; FRL–9951–44]

Aspergillus flavus strains TC16F, TC35C, TC38B, and TC46G; Temporary Exemptions From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes temporary exemptions from the requirement of a tolerance for residues of *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G in or on the food and feed commodities of corn, field; corn, pop; and corn, sweet when

used in accordance with the terms of Experimental Use Permit (EUP) No. 91163–EUP–1. Interregional Research Project Number 4 (IR–4) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting these temporary tolerance exemptions. This regulation eliminates the need under FFDCA to establish a maximum permissible level for residues of *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G when used under the terms of EUP No. 91163–EUP–1. The temporary tolerance exemptions expire on June 30, 2020.

DATES: This regulation is effective September 16, 2016. Objections and requests for hearings must be received on or before November 15, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0742, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2015–0742 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before November 15, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2015–0742, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background

In the **Federal Register** of February 9, 2016 (81 FR 6826) (FRL–9941–42), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 5E8397) by IR–4, Rutgers University, 500 College Rd. East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G in or on corn. That document referenced a summary of the petition prepared by the petitioner IR–4, which is available in the docket via *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

EPA changed the commodity name reflected in the tolerance exemption expression from "corn" to "food and feed commodities of corn, field; corn, pop; and corn, sweet" and changed "tolerance exemption" to "tolerance exemptions". The reasons for these changes are explained in Unit III.C.

III. Final Rule

A. EPA's Safety Determination

Section 408(r) of FFDCA authorizes EPA to establish a temporary exemption from the requirement of a tolerance for residues covered by an experimental use permit issued under the Federal Insecticide, Fungicide, and Rodenticide Act. That section states that the provisions of section 408(c)(2) of FFDCA apply to exemptions issued under FFDCA section 408(r). Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . ." Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider "available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity."

EPA evaluated the available toxicity and exposure data on *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. A full explanation of the data upon which EPA relied and its risk assessment based on that data can be found within the August 18, 2016, document entitled "Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G." This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

Based upon its evaluation, EPA concludes that *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G are not toxic, not pathogenic, and not infective. Although there may be some exposure to residues when used on corn in accordance with the terms of EUP No. 91163–EUP–1, there is a lack of concern due to the lack of potential for adverse effects. EPA also determined that retention of the Food Quality Protection Act (FQPA) safety factor was not necessary as part of the qualitative assessment conducted for *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G.

Based upon its evaluation, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G. Therefore, temporary exemptions from the requirement of a tolerance are established for residues of *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G in or on the food and feed commodities of corn, field; corn, pop; and corn, sweet when used in accordance with the terms of EUP No. 91163–EUP–1.

B. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes for the reasons contained in the August 18, 2016, document entitled "Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G" and because EPA is establishing temporary exemptions from the requirement of a tolerance without any numerical limitation.

C. Revisions to the Requested Tolerance Exemption

Two modifications have been made to the requested tolerance exemption. EPA changed "corn" to "food and feed commodities of corn, field; corn, pop; and corn, sweet" to align with the Agency's food and feed commodity vocabulary. EPA also changed "tolerance exemption" to "tolerance exemptions" as four different active ingredients are covered with this action.

IV. Statutory and Executive Order Reviews

This action establishes exemptions from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*) nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemptions in this action, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, EPA has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require EPA's consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 30, 2016.

Jack Housenger,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 180.1338 to subpart D to read as follows:

§ 180.1338 Aspergillus flavus strains TC16F, TC35C, TC38B, and TC46G; temporary exemptions from the requirement of a tolerance.

Temporary exemptions from the requirement of a tolerance are established for residues of *Aspergillus flavus* strains TC16F, TC35C, TC38B, and TC46G in or on the food and feed commodities of corn, field; corn, pop; and corn, sweet when used in accordance with the terms of Experimental Use Permit No. 91163–EUP–1. These temporary exemptions from the requirement of a tolerance expire on June 30, 2020.

[FR Doc. 2016–22357 Filed 9–15–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2013–0237; FRL–9951–08]

Ammonium Persulfate; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of ammonium persulfate (CAS Reg. No.7727–54–0) when used as an inert ingredient (preservative) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest, etc.) at a concentration not to exceed 0.05% by weight. Exponent, Inc., on behalf of Becker Underwood, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ammonium persulfate under the approved conditions.

DATES: This regulation is effective September 16, 2016. Objections and requests for hearings must be received on or before November 15, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2013–0237, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2013–0237 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before November 15, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2013–0237, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of June 5, 2013 (78 FR 33785) (FRL–9386–2), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 2E8096) by Exponent, Inc., 1150 Connecticut Ave., Suite 1100, Washington, DC 20036, on behalf of Becker Underwood, Inc., 801 Dayton Avenue, Ames, IA 50010. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of ammonium persulfate (CAS Reg. No. 7727–54–0) when used as an inert ingredient (preservative) in pesticide formulations applied to growing crops or raw agricultural commodities after harvest at a concentration not to exceed 0.05% by weight in pesticide formulations. That document referenced a summary of the petition prepared by Exponent, Inc., the petitioner, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . ."

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for ammonium persulfate including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with ammonium persulfate follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by ammonium persulfate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies

The acute oral and dermal rat lethal dose $(LD)_{50}$s are 495 milligram/kilogram body weight (mg/kg bw) and >2,000 mg/kg bw, respectively. The inhalation lethal concentration $(LC)_{50}$ for ammonium persulfate in rats is >2,950 mg/cubic meter (m^3). It is irritating to the eyes but not the skin. It is not a dermal sensitizer.

Several subchronic studies were available for review for the sodium, potassium and ammonium salts of persulfate. In a 28 day oral (diet) toxicity study in rats, toxicity was manifested as decreased relative adrenal weight at 600 parts per million (ppm) (82 mg/kg/day). The NOAEL was 300 ppm; equal to 41 mg/kg/day. In a 3 months oral (diet) toxicity study in dogs, toxicity was not observed at doses up to 333 mg/kg/day, the highest dose tested. In a toxicity study in rats, ammonium persulfate was administered via inhalation for 13 weeks then allowed a 6-week recovery period. Toxicity was manifested as rales, increased respiratory rate, inflammation of the trachea and bronchi/bronchioles, decreased body weight, and increased lung weight at 25 mg/m^3. The NOAEL was 10.3 mg/m^3.

The reproductive and developmental toxicity of ammonium persulfate has been tested in rats. Parental, offspring and reproduction toxicity was not observed at doses up to 250 mg/kg/day, the highest dose tested.

Available mutagenicity and genotoxicity studies included the Ames test, gene mutation and chromosomal aberration assays. Ammonium persulfate produced negative results in all of these studies.

Oral and inhalation studies of the carcinogenic and promoting potential of ammonium persulfate do not exist; however, the carcinogenic and promoting potential of ammonium persulfate was tested in a non-guideline study via the dermal route of exposure. In a tumor promotion study, mice were treated dermally with ammonium persulfate biweekly for 51 weeks. In another study, mice were treated topically with a solution of 200 mg/milliliter (mL) ammonium persulfate for 51 weeks. The incidence of tumors did not increase in either study.

Neurotoxicity and immunotoxicity studies were not available for review. However, evidence of neurotoxicity and immunotoxicity of ammonium persulfate was not observed in the submitted studies.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

There was no hazard attributable to a single exposure seen in the toxicity database for ammonium persulfate. Therefore, ammonium persulfate is not expected to pose an acute risk.

The NOAEL for ammonium persulfate was established at 300 ppm; equal to 41 mg/kg/day based on the 28-day repeat dose oral toxicity study in rats based on decreased relative adrenal weight at 600 ppm (82 mg/kg/day). The chronic risk assessment for ammonium persulfate is based on this endpoint and the chronic reference dose (cRfD) is 0.41 mg/kg/day. The additional Food Quality Protection Act (FQPA) uncertainty factor of 3X is applied for use of short-term study for a long-term risk assessment. EPA concluded that the uncertainty factor of 3X is adequate because the end point selected for the risk assessment is very conservative since no effects on absolute adrenal weight was observed; relative weight could be due to slight decrease in body weight; no other systemic toxicity was seen at this dose level and there were no systemic toxicity observed in a 90-day toxicity study in dogs which considered as long term study. Since the FQPA safety factor (SF) has been reduced to 3X, the cPAD is 0.14 mg/kg/day. The NOAEL for inhalation exposure has been established as 10.3 mg/m^3 (3 mg/kg/day) based on reversible rales and respiratory rate increases in rats. For dermal exposures, the NOAEL for ammonium persulfate is based on the chronic oral NOAEL with an assumption of 100% dermal adsorption.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to ammonium persulfate, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from ammonium persulfate in food as follows:

An acute dietary risk assessment was not conducted because no endpoint of concern following a single exposure was identified in the available studies. A chronic dietary exposure assessment was completed and performed using the Dietary Exposure Evaluation Model DEEM–FCID™, Version 3.16.which includes food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, "What We Eat In America", (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. In the absence of actual residue data, the inert ingredient evaluation is based on a highly conservative model that assumes that the residue level of the inert ingredient would be no higher than the highest established tolerance for an active ingredient on a given commodity. Implicit in this assumption is that there would be similar rates of degradation between the active and inert ingredient (if any) and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient. The model assumes 100 percent crop treated (PCT) for all crops and that every food eaten by a person each day has tolerance-level residues. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts" (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for ammonium persulfate, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

While there are no current or proposed residential uses for ammonium persulfate, it is possible that ammonium persulfate may be used as an inert ingredient in pesticide products for which short-term and intermediate-term residential exposures may result. In the absence of specific residential exposure scenarios, risk estimates for residential exposures to ammonium persulfate can be modeled based on occupational exposure assessments. Occupational exposure assessments for ammonium persulfate for occupational mixer/loader/applicator exposure and occupational post-application exposure for comparable use scenarios (*e.g.,* low pressure handwand turf application) with only baseline personal protective equipment result in MOEs of 10,000 or greater (*i.e.,* exposures are not of concern). Given the larger treatment areas and higher concentrations used in these occupational use pesticide products than would be seen in residential uses, MOEs for residential use scenarios would exceed 1,000 or more and therefore there are no concerns for residential exposures to ammonium sulfate.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found ammonium persulfate to share a common mechanism of toxicity with any other substances, and ammonium persulfate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that ammonium persulfate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased susceptibility of infants and children following exposure to ammonium persulfate. In the reproductive and developmental toxicity study of ammonium persulfate in rats, parental, offspring and reproduction toxicity was not observed at doses up to 250 mg/kg/day, the highest dose tested.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 3X. That decision is based on the following findings:

i. The toxicity database for ammonium persulfate is partially complete. The additional uncertainty FQPA factor of 3X is applied for use of short-term study for long term risk assessment.

ii. There is no indication that ammonium persulfate is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that ammonium persulfate results in increased susceptibility in rats in utero or in young in the reproductive and developmental screening study.

iv. There is no evidence of any triggers for immunotoxicity in the available database, therefore there is no need for an immunotoxicity study at this time or an additional UF factor to account for lack of an immunotoxicity study.

v. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to ammonium persulfate in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by ammonium persulfate.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, ammonium persulfate is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to ammonium persulfate from food and water will utilize <1% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure.

3. *Short- and Intermediate-term risk.* A short- & intermediate-term adverse effect was identified for ammonium persulfate. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. While there are no current or proposed residential uses for ammonium persulfate, it is possible that ammonium persulfate may be used as an inert ingredient in pesticide products for which short- and intermediate-term residential exposures may result. Margins of exposure (MOEs) for short- and intermediate-term residential use scenarios have been calculated and exceed 10,000 or more and therefore, since the level of concern is for MOEs of 300 or less, there are no concerns for residential exposures to ammonium persulfate.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of mutagenicity and lack of evidence of tumors in the tumor promoting studies via dermal route, and lack of carcinogenicity for sulfates and ammonia (break down products), ammonium persulfate is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to ammonium persulfate residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Although EPA is establishing a limitation on the amount of ammonium persulfate that may be used in pesticide formulations, an analytical enforcement methodology is not necessary for this exemption from the requirement of tolerance. The limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide for sale or distribution for use on growing crops with concentrations of ammonium persulfate exceeding 0.05% by weight of the formulation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for ammonium persulfate.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for ammonium persulfate (CAS Reg. No. 7727–54–0) when used as an inert ingredient (preservative) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest at a concentration not to exceed 0.05% by weight.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of

Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 1, 2016.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.910, add alphabetically the following inert ingredient to the table to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

Inert ingredients	Limits	Uses
* * * * * * *		
Ammonium persulfate (CAS Reg.No. 7727–54–0)	0.05%	Preservative
* * * * * * *		

[FR Doc. 2016–22366 Filed 9–15–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 90

[PS Docket Nos. 12–94, 06–229, 06–150; FCC 16–117]

Implementing Public Safety Broadband Provisions of the Middle Class Tax Relief and Job Creation Act of 2012

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) addresses the 758–769/788–799 MHz band, which the Commission licensed to the First Responder Network Authority (FirstNet) on a nationwide basis pursuant to the provisions of the Middle Class Tax Relief and Job Creation Act of 2012. We provide a mechanism to facilitate the relocation of the public safety narrowband incumbents currently operating on FirstNet's spectrum. We also affirmatively decline at this time to impose specific build-out requirements on FirstNet as a condition of renewal of its license.

DATES: Effective October 17, 2016.

FOR FURTHER INFORMATION CONTACT: Roberto Mussenden, Policy and Licensing Division, Public Safety and Homeland Security Bureau, (202) 418–1428.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order in PS Docket No. 12–94, FCC 16–117, adopted on August 24, 2016 and released on August 25, 2016. The document is available for download at *http://fjallfoss.fcc.gov/edocs_public/.* The complete text of this document is also available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *FCC504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

1. In 2013, the Commission's Notice of Proposed Rulemaking (NPRM) sought comment on implementation of certain provisions of the Public Safety Spectrum Act, including how to relocate narrowband incumbents operating on the spectrum licensed to FirstNet, and how to address FirstNet's renewal expectations, including whether FirstNet should be subject to Commission-initiated build-out requirements.

2. In the Report and Order, the Commission permits narrowband incumbents to remain on FirstNet's licensed spectrum until August 31,

2017, after which they will be required to vacate absent FirstNet's express consent to remain longer. In addition, the Commission prohibits continued operation by incumbents that have either previously discontinued operations or that are no longer in operation after the effective date of the Report and Order, and prohibits all narrowband incumbents from deploying additional facilities on FirstNet's licensed spectrum beyond those currently deployed as of the adoption date of the Report and Order. Accordingly, as of the adoption date of the Report and Order, the Commission terminates all authority to initiate new deployments pursuant to waivers previously granted by the Commission or Bureau, which had authorized deployment beyond the 2007 deadline.

3. The Commission states specifies that under existing rules, any TV studio-transmitter links, TV relay stations, and TV translator relay stations operating on the FirstNet spectrum under Part 74, subpart G of the Commission's rules must cease operations within 120 days of receiving notice from FirstNet.

4. The Commission concludes that there is no need or legal basis at this time for it to play a role in resolving disputes between FirstNet and incumbent licensees over relocation costs. The Commission also finds there is no need at this time to establish additional Commission rules to ensure rural coverage or any of the other requirements for renewal of FirstNet's license.

Procedural Matters

A. Final Regulatory Flexibility Analysis

5. The Final Regulatory Flexibility Analysis required by section 604 of the Regulatory Flexibility Act, 5 U.S.C. 604, is included in Appendix D of the Report and Order.

B. Paperwork Reduction Act of 1995 Analysis

6. The Report and Order document does not contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13.

Final Regulatory Flexibility Analysis

7. As required by the Regulatory Flexibility Act (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was incorporated into the NPRM of this proceeding. The Commission sought written public comment on the IRFA. The RFA requires that an agency prepare a regulatory flexibility analysis for notice-and-comment rulemaking proceedings, unless the agency certifies that "the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." The RFA generally defines "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act. A "small business concern" is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA). The present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

A. Need for, and Objectives of, the Proposed Rules

8. In the Report and Order, we regulate the transition of different classes of incumbents now occupying portions of the spectrum to be licensed to FirstNet. These actions are based on our established authority under the Communications Act to regulate use of the spectrum consistent with the public interest, convenience and necessity and our authority under the Public Safety Spectrum Act "to take all actions necessary to facilitate the transition" of the existing public safety broadband spectrum to FirstNet.

B. Summary of Significant Issues Raised by Public Comments in Response to the IRFA

9. There were no comments filed that specifically addressed the rules and policies proposed in the IRFA.

C. Description and Estimate of the Number of Small Entities to Which the Rules Will Apply

10. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act. A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

11. *Small Businesses, Small Organizations, and Small Governmental Jurisdictions.* Our action may, over time, affect small entities that are not easily categorized at present. We therefore describe here, at the outset, three comprehensive, statutory small entity size standards. First, nationwide, there are a total of approximately 27.5 million small businesses, according to the SBA. In addition, a "small organization" is generally "any not-for-profit enterprise which is independently owned and operated and is not dominant in its field." Nationwide, as of 2007, there were approximately 1,621,315 small organizations. Finally, the term "small governmental jurisdiction" is defined generally as "governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand." Census Bureau data for 2011 indicate that there were 89,476 local governmental jurisdictions in the United States. We estimate that, of this total, as many as 88,506 entities may qualify as "small governmental jurisdictions." Thus, we estimate that most governmental jurisdictions are small.

12. *Public Safety Radio Licensees.* As a general matter, Public Safety Radio Licensees include police, fire, local government, forestry conservation, highway maintenance, and emergency medical services. For the purpose of determining whether a Public Safety Radio Licensee is a small business as defined by the SBA, we use the broad census category, Wireless Telecommunications Carriers (except Satellite). This definition provides that a small entity is any such entity employing no more than 1,500 persons. With respect to local governments, in particular, since many governmental entities comprise the licensees for these services, we include under public safety services the number of government entities affected. According to Commission records, there are a total of approximately 133,870 licenses within these services. There are 2,442 licenses in the 4.9 GHz band, based on an FCC Universal Licensing System search of May 23, 2012. We estimate that fewer than 2,442 public safety radio licensees hold these licenses because certain entities may have multiple licenses.

13. *Regional Planning Committees.* Neither the Commission nor the SBA has developed a small business size standard specifically applicable to Regional Planning Committees (RPCs) and the National Regional Planning Council (NRPC). As described by the NRPC, "[t]he National Regional Planning Council (NRPC) is an advocacy body formed in 2007 that supports public safety communications spectrum management by Regional Planning Committees (RPC) in the 700 MHz and

800 MHz NPSPAC public safety spectrum as required by the Federal Communications Commission.'' The NRPC states that ''Regional Planning Committees consist of public safety volunteer spectrum planners and members that dedicate their time, in addition to the time spent in their regular positions, to coordinate spectrum efficiently and effectively for the purpose of making it available to public safety agency applicants in their respective region.'' There are 54 formed RPCs and one unformed RPC. The Commission has not developed a small business size standard specifically applicable to RPCs and the NRPC. The SBA rules, however, contain a definition for Wireless Telecommunications Carriers (except Satellite) which encompasses business entities engaged in radiotelephone communications employing no more than 1,500 persons. Under this category and size standard, we estimate that all of the RPCs and the NRPC can be considered small.

14. *Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing.* The Census Bureau defines this category as follows: ''This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: Transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment.'' The SBA has developed a small business size standard for Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, which is: All such firms having 750 or fewer employees. According to Census Bureau data for 2007, there were a total of 939 establishments in this category that operated for part or all of the entire year. According to Census bureau data for 2007, there were a total of 919 firms in this category that operated for the entire year. Of this total, 771 had fewer than 100 employees and 148 had more than 100 employees. Thus, under that size standard, the majority of firms can be considered small.

D. Description of Projected Reporting, Recordkeeping and Other Compliance Requirements

15. Our actions will not require any reporting, recordkeeping or other compliance requirements.

E. Steps Taken To Minimize Significant Economic Impact on Small Entities and Significant Alternatives Considered

16. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

17. Nonetheless, we recognized there may arguably be a significant number of small entities currently operating in FirstNet's spectrum that would need relocation. Thus, one mechanism the Commission considered to minimize the economic burden on incumbent operators was to consider whether FirstNet or some third party source could fund relocation, thereby relieving any incumbent small entities of this potentially substantial economic burden. It also evaluated whether FirstNet could accommodate incumbent narrowband operations within a portion of its licensed spectrum, either indefinitely or on a transitional basis.

F. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

18. None.

G. Report to Congress

19. The Commission will not send a copy of this Report and Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A), because the Commission did not adopt any rules of particular applicability.

Ordering Clauses

20. Accordingly, *it is ordered* that, pursuant to sections 1, 4(i), 4(j), 301, 303, and 316 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 154(j), 301, 303, 316, as well as Title VI of the Middle Class Tax Relief and Job Creation Act of 2012, Public Law 112–96, 126 Stat. 156, the *Report and Order is hereby adopted.*

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2016–22361 Filed 9–15–16; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150916863–6211–02]

RIN 0648–XE878

Fisheries of the Exclusive Economic Zone Off Alaska; Exchange of Flatfish in the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; reallocation.

SUMMARY: NMFS is exchanging allocations of Amendment 80 cooperative quota (CQ) for Amendment 80 acceptable biological catch (ABC) reserves. This action is necessary to allow the 2016 total allowable catch of flathead sole, rock sole, and yellowfin sole in the Bering Sea and Aleutian Islands management area to be harvested.

DATES: Effective September 16, 2016, through December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the Bering Sea and Aleutian Islands management area (BSAI) according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2016 flathead sole, rock sole, and yellowfin sole Amendment 80 allocations of the total allowable catch (TAC) specified in the BSAI are 13,753 metric tons (mt), 44,990 mt, and 110,113 mt as established by the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016). The 2016 flathead sole, rock sole, and yellowfin sole

Amendment 80 ABC reserves are 40,408 mt, 92,872 mt, and 60,456 mt as established by the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016).

The Alaska Seafood cooperative has requested that NMFS exchange 3,900 mt of flathead sole and 1,025 mt of rock sole Amendment 80 allocations of the TAC for 4,925 mt of yellowfin sole Amendment 80 ABC reserves under § 679.91(i). Therefore, in accordance with § 679.91(i), NMFS exchanges 3,900 mt of flathead sole and 1,025 mt of rock sole Amendment 80 allocations of the TAC for 4,925 mt of yellowfin sole Amendment 80 ABC reserves in the BSAI. This action also decreases and increases the TACs and Amendment 80 ABC reserves by the corresponding amounts. Tables 11 and 13 of the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016) and as revised (81 FR 62833, September 13, 2016) are further revised as follows:

TABLE 11—FINAL 2016 COMMUNITY DEVELOPMENT QUOTA (CDQ) RESERVES, INCIDENTAL CATCH AMOUNTS (ICAS), AND AMENDMENT 80 ALLOCATIONS OF THE ALEUTIAN ISLANDS PACIFIC OCEAN PERCH, AND BSAI FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE TACS

[Amounts are in metric tons]

Sector	Pacific ocean perch			Flathead sole	Rock sole	Yellowfin sole
	Eastern Aleutian District	Central Aleutian District	Western Aleutian District	BSAI	BSAI	BSAI
TAC	7,900	7,000	9,000	16,685	55,425	149,990
CDQ	845	749	963	1,832	5,460	16,473
ICA	200	75	10	5,000	6,000	3,500
BSAI trawl limited access	685	618	161	0	0	14,979
Amendment 80	6,169	5,558	7,866	9,853	43,965	115,038
Alaska Groundfish Cooperative	3,271	2,947	4,171	1,411	11,129	43,748
Alaska Seafood Cooperative	2,898	2,611	3,695	8,442	32,836	71,290

Note: Sector apportionments may not total precisely due to rounding.

TABLE 13—FINAL 2016 AND 2017 ABC SURPLUS, COMMUNITY DEVELOPMENT QUOTA (CDQ) ABC RESERVES, AND AMENDMENT 80 ABC RESERVES IN THE BSAI FOR FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE

[Amounts are in metric tons]

Sector	2016 Flathead sole	2016 Rock sole	2016 Yellowfin sole	2017 Flathead sole	2017 Rock sole	2017 Yellowfin sole
ABC	66,250	161,100	211,700	64,580	145,000	203,500
TAC	16,685	55,425	149,990	21,000	57,100	144,000
ABC surplus	49,565	105,675	61,710	43,580	87,900	59,500
ABC reserve	49,565	105,675	61,710	43,580	87,900	59,500
CDQ ABC reserve	5,257	11,778	6,179	4,663	9,405	6,367
Amendment 80 ABC reserve	44,308	93,897	55,531	38,917	78,495	53,134
Alaska Groundfish Cooperative for 2016[1]	4,145	22,974	24,019	n/a	n/a	n/a
Alaska Seafood Cooperative for 2016[1]	40,163	70,923	31,512	n/a	n/a	n/a

[1] The 2017 allocations for Amendment 80 species between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2016.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the flatfish exchange by the Alaska Seafood cooperative the BSAI. Since these fisheries are currently open, it is important to immediately inform the industry as to the revised allocations. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery, to allow the industry to plan for the fishing season, and to avoid potential disruption to the fishing fleet as well as processors. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of September 7, 2016.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 13, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–22338 Filed 9–15–16; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 81, No. 180
Friday, September 16, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 984

[Doc. No. AMS–SC–16–0062; SC16–984–2 PR]

Walnuts Grown in California; Increased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement a recommendation from the California Walnut Board (Board) to increase the assessment rate established for the 2016–17 and subsequent marketing years from $0.0379 to $0.0465 per kernelweight pound of assessable walnuts. The Board locally administers the marketing order and is comprised of growers and handlers of walnuts operating within the area of production. Assessments upon walnut handlers are used by the Board to fund reasonable and necessary expenses of the program. The marketing year begins September 1 and ends August 31. The assessment rate would remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Comments must be received by October 17, 2016.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or Internet: *http://www.regulations.gov*. Comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov*. All comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Terry Vawter, Senior Marketing Specialist, or Jeffrey Smutny, Regional Director, California Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 487–5901, Fax: (559) 487–5906, or Email: *Terry.Vawter@ams.usda.gov* or *Jeffrey.Smutny@ams.usda.gov*.

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Richard.Lower@ams.usda.gov*.

SUPPLEMENTARY INFORMATION: This proposed rule is issued under Marketing Order No. 984, as amended (7 CFR part 984), regulating the handling of walnuts grown in California, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the "Act."

The Department of Agriculture (USDA) is issuing this proposed rule in conformance with Executive Orders 12866, 13563, and 13175.

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the order now in effect, California walnut handlers are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the assessment rate as proposed herein would be applicable to all assessable walnuts beginning on September 1, 2016, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This proposed rule would increase the assessment rate for the 2016–17 and subsequent marketing years from $0.0379 to $0.0465 per kernelweight pound of assessable walnuts.

The order provides authority for the Board, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. All members of the Board, but one, are growers and handlers of California walnuts. They are familiar with the Board's needs and with the costs for goods and services in their local area and are thus in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2015–16 and subsequent marketing years, the Board recommended, and USDA approved, an assessment rate of $0.0379 per kernelweight pound of assessable walnuts that would continue in effect from year to year unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Board or other information available to USDA.

The Board met on June 9, 2016, and unanimously recommended 2016–17 expenditures of $23,143,050 and an assessment rate of $0.0465 per kernelweight pound of assessable walnuts. In comparison, last year's budgeted expenditures were $22,668,980. The assessment rate of $0.0465 is $0.0086 per pound higher than the rate currently in effect. The quantity of assessable walnuts for the 2016–17 marketing year is estimated at 553,000 tons inshell or 497,700,000 kernelweight pounds, which is the five-year average of walnut production. At the recommended higher assessment rate of $0.0465 per kernelweight pound, the Board should collect approximately $23,143,050 in assessment income, making income and expenses equal. The Board estimates it will begin the 2016–17 marketing year with $9,827,284 in their monetary reserve, which is well within the requirements of the order.

The Board noted that sales of California walnuts in the domestic market have been declining in recent years, and embarked upon an enhanced market development and promotion program that would reverse the trend. Noting that making such a commitment for a single year would likely not result in long-term gains, they voted to continue such market development and promotion programs yet another year. Thus, they are maintaining their programs at a level near that of the 2015–16 marketing year.

In addition, personnel changes will result in an overlap of duties and expenses, as some positions will be added so that experience and continuity can be maintained in spite of staff retirements. Thus, employee costs are expected to be higher this marketing year. Added to that, the implementation of the Food Safety Modernization Act (FSMA) may result in added costs to the industry, and in some cases, to the Board as well. For that reason, the Grades and Standards Committee and the Research Committee requested increased budgets.

The following table compares major budget expenditures recommended by the Board for the 2015–16 and 2016–17 marketing years:

Budget expense categories	2015–16	2016–17
Employee Expenses	$ 1,846,500	$ 2,292,000
Travel/Board Expenses/Annual Audit	191,000	206,000
Office Expenses	254,000	262,000
Controlled Purchases	10,000	10,000
Crop Acreage Survey	100,000	0
Crop Estimate	130,000	130,000
Production Research Director	94,500	175,000
Production Research	1,700,000	1,800,000
Sustainability Project	75,000	75,000
Grades and Standards Research	600,000	800,000
Domestic Market Development	18,478,440	18,398,040
Reserve for Contingency	32,790	59,010

The assessment rate recommended by the Board was derived by dividing anticipated assessment revenue needed by estimated shipments of California walnuts certified as merchantable. The 553,000 ton (inshell) estimate for merchantable shipments is an average of shipments during three prior years. Pursuant to § 984.51(b) of the order, this figure is converted to a merchantable kernelweight basis using a factor of 0.45 (553,000 tons × 2,000 pounds per ton × 0.45), which yields 497,700,000 kernelweight pounds. At $0.0465 per pound, the new assessment rate should generate $23,143,050 in assessment income, which is equal to estimated expenses.

Section 984.69 of the order authorizes the Board to carry over excess funds into subsequent marketing years as a reserve, provided that funds already in the reserve do not exceed approximately two years' budgeted expenses. Current reserve funds total $9,827,284 and are well within that requirement.

The proposed assessment rate would continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Board or other available information.

Although this assessment rate would be effective for an indefinite period, the Board would continue to meet prior to or during each marketing year to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Board meetings are available from the Board or USDA. Board meetings are open to the public and interested persons may express their views at these meetings. USDA would evaluate Board recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The Board's 2016–17 budget and those for subsequent marketing years would be reviewed, and, as appropriate, approved by USDA.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this proposed rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 5,700 growers of California walnuts in the production area and approximately 90 handlers subject to regulation under the order. The Small Business Administration (SBA) defines small agricultural businesses (13 CFR 121.201) as those having annual receipts of less than $750,000, and small agricultural service firms are defined as those having annual receipts of less than $7,500,000.

According to USDA's National Agricultural Statistics Service's (NASS's) 2012 Census of Agriculture, approximately 86 percent of California's walnut farms were smaller than 100 acres. Further, NASS reports that the average yield for 2014 was 1.97 tons per acre, and the average price received for 2014 was $3,230 per ton.

A 100-acre farm with an average yield of 1.97 tons per acre would therefore have been expected to produce about 197 tons of walnuts during 2014–15 marketing year. At $3,230 per ton, that farm's production would have had an approximate value of $636,310. Since Census of Agriculture information indicates that the majority of California's walnut farms are smaller than 100 acres, it could be concluded that the majority of the growers had receipts of less than $636,310 in 2014–15, which is well below the SBA threshold of $750,000. Thus, the majority of California's walnut growers would be considered small growers according to SBA's definition.

According to information supplied by the Board, approximately two-thirds of California's walnut handlers shipped merchantable walnuts valued under $7,500,000 during the 2014–15 marketing year, and would, therefore, be considered small businesses according to the SBA definition.

This proposed rule would increase the assessment rate and collected from handlers for the 2016–17 and subsequent marketing years from $0.0379 to $0.0465 per kernelweight pound of assessable walnuts. The Board unanimously recommended 2016–17 expenditures of $23,143,050 and an assessment rate of $0.0465 per kernelweight pound of assessable walnuts. The proposed assessment rate of $0.0465 is $0.0086 higher than the 2015–16 rate. The quantity of assessable walnuts for the 2016–17 marketing year is estimated at 553,000 tons inshell weight, or 497,700,000 kernelweight pounds. Thus, the $0.0465 rate should provide $23,143,050 in assessment income.

The increased assessment rate is due to continuing domestic marketing and promotion programs, as well as to increased personnel and committee expenses. The Board believes that California walnut sales can be improved in the domestic market through continued promotional activities. In addition, the Grades and Standards and Research Committees have asked for additional funds in case the implementation of FSMA requires new methods or processes for growing, harvesting, and shipping walnuts.

The major expenses for the 2016–17 marketing year include: $2,292,000 for employee expenses; $206,000 for travel, board expenses, and annual audit expenses; $262,000 for office expenses; $10,000 for controlled purchases; $0 for the crop acreage survey; $130,000 for the crop estimate; $175,000 for the salary of the Production Research Director; $1,800,000 for production research; $75,000 for sustainability; $800,000 for grades and standards research; $18,398,040 for domestic market development projects; and $59,010 for the contingency reserve.

By comparison, the major expenses for the 2015–16 marketing year include: $1,846,500 for employee expenses; $191,000 for travel, board expenses, and annual audit expenses; $254,000 for office expenses; $10,000 for controlled purchases; $100,000 for the crop acreage survey; $130,000 for the crop estimate; $94,500 for the salary of the Production Research Director; $1,700,000 for production research; $75,000 for sustainability; $600,000 for grades and standards research; $18,478,440 for domestic market development projects; and $32,790 for the contingency reserve.

The Board reviewed and unanimously recommended 2016–17 expenditures of $23,143,050. Prior to arriving at this budget, the Board considered a recommendation from the Budget and Personnel Committee (committee), which also reviewed the proposed budget. The committee debated the relative value of the increased assessment rate, given the focus on domestic promotion programs. They also considered information from various other committees, who deliberated and formulated their own budgets of expenses and made their recommendations to the committee. Those committees include the Market Development, Production Research, and Grades and Standards Committees.

The Budget and Personnel Committee considered alternative expenditure levels, such as reducing the proposed budgets recommended by the other committees, and changing the funding for domestic marketing projects, as well as not increasing the assessment rate. The committee ultimately decided that the proposed expenditures and assessment rate were reasonable and necessary to assist in improving domestic sales, maintaining staff continuity, and preparing for potential FSMA mandates. Thus, the committee unanimously agreed to recommend the proposed budget to the Board.

The assessment rate of $0.0465 per kernelweight pound of assessable walnuts was derived by dividing anticipated assessment revenue needed by expected shipments of California walnuts certified as merchantable. Merchantable shipments for the year are estimated at 497,700,000 pounds. It was determined that $23,143,050 in assessment income was needed, and assessment income would equal expenses of $23,143,050.

Unexpended funds may be retained in a financial reserve, provided that funds in the financial reserve do not exceed approximately two years' budgeted expenses.

According to NASS, the season average grower prices for the years 2013 and 2014 were $3,710 and $3,230 per ton, respectively. These prices provide a range within which the 2016–17 season average price could fall. Dividing these average grower prices by 2,000 pounds per ton provides an inshell price per pound range of $1.62 to $1.86. Dividing these inshell per pound prices by the 0.45 conversion factor (inshell to kernelweight) established in the order yields a 2016–17 price range estimate of $3.60 to $4.13 per kernelweight pound of assessable walnuts.

To calculate the percentage of grower revenue represented by the assessment rate, the assessment rate of $0.0465 per kernelweight pound is divided by the low and high estimates of the price range. The estimated assessment revenue for the 2016–17 marketing year as a percentage of total grower revenue will thus likely range between 1.13 and 1.29 percent.

This action would increase the assessment obligation imposed on handlers. While assessments impose some additional costs on handlers, the costs are minimal and uniform on all handlers. However, these costs would be offset by the benefits derived by the operation of the marketing order. In addition, the Board's meeting was widely publicized throughout the California walnut industry, and all interested persons were invited to attend the meeting and encouraged to participate in Board deliberations on all issues. Like all Board meetings, the June 9, 2016, meeting was a public meeting and all entities, both large and small, were free to express views on this issue. Finally, interested persons are invited to submit comments on this proposed rule, including the regulatory and informational impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0178 (Walnuts Grown in California). No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would impose no additional reporting or recordkeeping requirements on either small or large California walnut handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this action.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 30-day comment period is provided to allow interested persons to respond to this proposed rule. Thirty days is deemed appropriate because: (1) The 2016–17 marketing year begins on September 1, 2016, and the marketing order requires that the rate of assessment for each marketing year apply to all assessable walnuts handled during the year; and (2) handlers are aware of this action, which was unanimously recommended by the Board at a public meeting and is similar to other assessment rate actions issued in past years.

List of Subjects in 7 CFR Part 984

Marketing agreements, Nuts, Reporting and recordkeeping requirements, Walnuts.

For the reasons set forth in the preamble, 7 CFR part 984 is proposed to be amended as follows:

PART 984—WALNUTS GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 984 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 984.347 is revised to read as follows:

§ 984.347 Assessment rate.

On and after September 1, 2016, an assessment rate of $0.0465 per kernel weight pound is established for California merchantable walnuts.

Dated: September 12, 2016.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2016–22249 Filed 9–15–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 984

[Doc. No. AMS–SC–16–0053, SC–16–984–1 PR]

Walnuts Grown in California; Proposed Amendment to Marketing Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule invites public comments on a proposed amendment to Marketing Order No. 984, which regulates the handling of walnuts grown in California. The California Walnut Board (Board), which is responsible for the local administration of the order and is comprised of walnut producers and handlers operating within the production area, recommended an amendment that would authorize the Board to borrow from a commercial lending institution to fund operations and marketing/research expenses. Allowing the Committee to utilize this customary business practice would provide flexibility for the Board while increasing its effectiveness.

DATES: Comments must be received by November 15, 2016.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or Internet: *http://www.regulations.gov.* Comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov.* All comments submitted in response to this proposal will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Geronimo Quinones, Marketing Specialist, or Michelle P. Sharrow, Rulemaking Branch Chief, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; 1400 Independence Avenue SW., Stop 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Geronimo.Quinones@ams.usda.gov* or *Michelle.Sharrow@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Antoinette Carter, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Antoinette.Carter@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This proposal is issued under Marketing Order No. 984, as amended (7 CFR part 984), regulating the handling of walnuts grown in California, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the "Act."

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 12866, 13563, and 13175.

This proposal has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

Section 1504 of the Food, Conservation, and Energy Act of 2008 (2008 Farm Bill) (Pub. L. 110–246) amended section 18c(17) of the Act, which in turn required the addition of supplemental rules of practice to 7 CFR part 900 (73 FR 49307; August 21, 2008). The additional supplemental rules of practice authorize the use of informal rulemaking (5 U.S.C. 553) to amend Federal fruit, vegetable, and nut marketing agreements and orders. USDA may use informal rulemaking to amend marketing orders based on the nature and complexity of the proposed amendments, the potential regulatory and economic impacts on affected entities, and any other relevant matters.

AMS has considered these factors and has determined that the amendment proposal is not unduly complex and the nature of the proposed amendment is appropriate for utilizing the informal rulemaking process to amend the order. A discussion of the potential regulatory and economic impacts on affected entities is discussed later in the "Initial Regulatory Flexibility Analysis" section of this rule.

The proposed amendment was unanimously recommended by the Board following deliberations at a public meeting held on February 19,

2016. Currently, the order does not allow the Board to borrow funds from a commercial lending institution. Allowing the Board to utilize this customary business practice would help to improve administration of the order by providing it with the means for ensuring continuity of operations when its obligations are greater than available assessment revenue and reserve funds.

Proposal—Borrowing From a Commercial Lending Institution

Section 984.69 of the order, Assessments, authorizes the Board to collect assessments from handlers to administer the program.

This proposal would provide the Board with authority to borrow from a commercial lending institution during times of cash shortages. In the past, the Board has utilized reserve funds collected through handler assessments, to help finance the advertising/marketing program. However, due to the increased size of the domestic advertising program; relying on reserve funds as a means to meet obligations would make the program unsustainable in the long term. History shows, the most costly part of the program runs during the first six months of the marketing year and those expenditures must be paid by mid-year. Since the payments must be made before all assessment fees are invoiced and collected, a cash shortage may occur during the year. Authorizing the Board to borrow from a commercial lending institution would help manage and sustain the program during times of low income while also ensuring continuity of operations.

Therefore, for the reasons stated above, it is proposed that § 984.69, Assessments, be amended by adding a new paragraph that would provide the Board with authority to borrow from a commercial lending institution when no other funding is available.

Initial Regulatory Flexibility Analysis

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 5,700 growers of California walnuts in the production area and approximately 90 handlers subject to regulation under the marketing order. The Small Business Administration (SBA) defines small agricultural producers as those having annual receipts of less than $750,000, and small agricultural service firms are defined as those having annual receipts of less than $7,500,000. (13 CFR 121.201)

According to USDA's National Agricultural Statistics Service's (NASS's) 2012 Census of Agriculture, approximately 86 percent of California's walnut farms were smaller than 100 acres. Further, NASS reports that the average yield for 2014 was 1.97 tons per acre, and the average price received for 2014 was $3,230 per ton.

A 100-acre farm with an average yield of 1.97 tons per acre would therefore have been expected to produce about 197 tons of walnuts during 2014–15 marketing year. At $3,230 per ton, that farm's production would have had an approximate value of $636,310. Since Census of Agriculture information indicates that the majority of California's walnut farms are smaller than 100 acres, it could be concluded that the majority of the growers had receipts of less than $636,310 in 2014–15, which is well below the SBA threshold of $750,000. Thus, the majority of California's walnut growers would be considered small growers according to SBA's definition.

According to information supplied by the Board, approximately two-thirds of California's walnut handlers shipped merchantable walnuts valued under $7,500,000 during the 2014–15 marketing year; and would, therefore, be considered small handlers according to the SBA definition.

The proposed rule would authorize the Board to borrow from commercial lending institutions. This would help to ensure continuity in operations.

The Board reviewed and identified the most costly portion of its domestic advertising program. That portion of the program operates during the first six months of the Board's marketing year and costs must be paid by mid-year. Since assessment revenues are collected throughout the marketing year, not enough is on hand when these large payments are due. In the past, the Board has used reserve funds to help pay for marketing and advertising expenses. However, due to the increased size of the advertising program, the Board cannot rely on reserve funds to cover the costs. Based on this fact, the Board believes the program could become unsustainable in the long term.

While this action could result in a temporary increase in handler assessment costs, these increases would be small and uniform on all handlers and proportional to the size of their businesses. These costs are expected to be offset by the benefits derived from a sustained marketing and advertising program. Additionally, these costs would help to ensure that the Board has sufficient funds to meet its financial obligations. Such stability is expected to allow the Board to conduct a program that would benefit all entities, regardless of size. California walnut producers should see an improved business environment and a more sustainable business model because of the improved business efficiency.

Alternatives were considered to this proposal, including making no change at this time. However, the Board believes it would be beneficial to have the means and funds necessary to effectively administer the program.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0178, "Vegetable and Specialty Crops." No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would impose no additional reporting or recordkeeping requirements on either small or large California walnut handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

The Board's meeting was widely publicized throughout the California walnut production area. All interested persons were invited to attend the meeting and encouraged to participate in Board deliberations on this issue. Like all Board meetings, the February 19, 2016, meeting was public, and all entities, both large and small, were encouraged to express their views on the proposal.

Finally, interested persons are invited to submit comments on the proposed amendment to the order, including comments on the regulatory and informational impacts of this action on small businesses.

Following analysis of any comments received on the proposed amendment, AMS will evaluate all available information and determine whether to proceed. If appropriate, a proposed rule and referendum order would be issued, and producers would be provided the opportunity to vote for or against the proposed amendment. Information about the referendum, including dates and voter eligibility requirements, would be published in a future issue of the **Federal Register**. A final rule would then be issued to effectuate the amendment if favored by producers participating in the referendum.

AMS is committed to complying with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this action. A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/MarketingOrdersSmallBusinessGuide.* Any questions about the compliance guide should be sent to Antoinette Carter at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

General Findings

The findings hereinafter set forth are supplementary to the findings and determinations which were previously made in connection with the issuance of the marketing order; and all said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

1. The marketing order as hereby proposed to be amended, and all of the terms and conditions thereof, would tend to effectuate the declared policy of the Act;

2. The marketing order as hereby proposed to be amended regulates the handling of walnuts grown in California and is applicable only to persons in the respective classes of commercial and industrial activity specified in the marketing order;

3. The marketing order as hereby proposed to be amended is limited in application to the smallest regional production area which is practicable, consistent with carrying out the declared policy of the Act, and the issuance of several orders applicable to subdivisions of the production area would not effectively carry out the declared policy of the Act;

4. The marketing order as hereby proposed to be amended prescribes, insofar as practicable, such different terms applicable to different parts of the production area as are necessary to give due recognition to the differences in the production and marketing of walnuts produced or packed in the production area; and

5. All handling of walnuts produced or packed in the production area as defined in the marketing order is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

A 60-day comment period is provided to allow interested persons to respond to the proposal. Any comments received on the amendment proposed in this rule will be analyzed, and if AMS determines to proceed based on all the information presented, a producer referendum would be conducted to determine producer support for the proposed amendment. If appropriate, a final rule would then be issued to effectuate the amendment favored by producers participating in the referendum.

List of Subjects in 7 CFR Part 984

Marketing agreements, Nuts, Reporting and recordkeeping requirements, Walnuts.

For the reasons set forth in the preamble, 7 CFR part 984 is proposed to be amended as follows:

PART 984—WALNUTS GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 984 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Amend § 984.69 by redesignating paragraph (d) as (e) and adding a new paragraph (d) to read as follows:

§ 984.69 Assessments.

* * * * *

(d) To provide funds for the administration of the provisions of this part during the part of a fiscal period when neither sufficient operating reserve funds nor sufficient revenue from assessments on the current season's certifications are available, the Board may accept payment of assessments in advance or may borrow money from a commercial lending institution for such purposes.

* * * * *

Dated: September 12, 2016.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2016–22247 Filed 9–15–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 989 and 999

[Doc. No. AMS–SC–16–0065; SC16–989–2 PR]

Raisins Produced From Grapes Grown in California and Imported Raisins; Removal of Language

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule invites comments on a recommendation by the Raisin Administrative Committee (Committee) to the remove the term "midget" from the minimum grade standards of the California raisin marketing order (order). The marketing order regulates the handling of raisins produced from grapes grown in California, and is administered locally by the Committee. Recently, the U.S. Standards for Grades of Processed Raisins (standards) were amended to remove the word "midget." The proposed change would make the marketing order consistent with the amended standards. Furthermore, this rule would make a corresponding change to the raisin import regulation as required by the Agricultural Marketing Agreement Act of 1937, as amended, when changes are made to the size, grade, maturity, or quality requirements of the order.

DATES: Comments must be received by October 17, 2016.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or Internet: *http://www.regulations.gov.* All comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed on the Internet at: *http://www.regulations.gov.* All comments submitted in response to this proposal will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Maria Stobbe, Marketing Specialist, or Jeffery Smutny, Regional Director, California Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 487–5901, Fax: (559) 487–5906, or Email: *Maria.Stobbe@ams.usda.gov* or *Jeffrey.Smutny@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Richard.Lower@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This proposal is issued under Marketing Agreement and Marketing Order No. 989, both as amended (7 CFR part 989), regulating the handling of raisins produced from grapes grown in California, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the "Act."

This proposed rule is also issued under section 8e of the Act, which provides that whenever certain specified commodities, including raisins, are regulated under a Federal marketing order, imports of these commodities into the United States are prohibited unless they meet the same or comparable grade, size, quality, or maturity requirements as those in effect for the domestically-produced commodities.

The Department of Agriculture (USDA) is issuing this proposed rule in conformance with Executive Orders 12866, 13563, and 13175.

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This proposed rule is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

There are no administrative procedures which must be exhausted prior to any judicial challenge to the provisions of import regulations issued under section 8e of the Act.

This proposal invites comments on the removal of the term "midget" from § 989.702(a) of the order and § 999.300(b)(1) of the import regulations. This action would make the order and the import regulations consistent with the recent change to the standards.

The Committee unanimously recommended that the term "midget" be removed from the order at a meeting on June 26, 2014. At a subsequent meeting on August 14, 2014, the committee also unanimously recommended that the word "midget" be removed from the standards. As required under the Act, the import regulations must be consistent with the changes to the order. In this instance, the order must be consistent with changes to the standards.

Paragraph (a) of § 989.702 of the order specifies minimum grade standards for packed Natural (sun-dried) Seedless (NS) raisins, requiring that small (midget)-sized raisins shall meet U.S. Grade C tolerances with respect to pieces of stem, and underdeveloped and substandard raisins. The word "midget" is redundant to the term "small," and its removal is insignificant.

Pursuant to the recommendation of the Committee and consistent with the recent amendment of the standards, the word "midget" is proposed to be removed from the order language.

The Committee's recommendation to delete the word "midget" from the order and the standards necessitates a corresponding change to the import requirements.

Under the raisin import regulations, in paragraph (b)(1) of § 999.300, raisins imported into the United States are required to meet the same or comparable grade, size, quality, or maturity requirements as those in effect for the domestically-produced commodities, when such commodities are regulated under an order. With the removal of the word "midget" from both the standards and the order, removal of "midget" is required under the import regulations.

Removal of the word "midget" should not impact the application of the order or the import regulations, since the word "midget" is redundant and appears in parentheses after the word "small." Thus, removing the word "midget" has no effect on interpretation of the order or the import regulations; and, therefore, has no effect on raisin importers.

The final rule removing the word "midget" from the standards was published in the **Federal Register** on June 23, 2016 (81 FR 40779). Thus, this proposal would make the order and the import regulations consistent with the standards, as recently revised.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 3,000 California raisin producers and 24 handlers subject to regulation under the marketing order. The Small Business Administration defines small agricultural producers as those having annual receipts less than $750,000, and defines small agricultural service firms, such as handlers and importers, as those whose annual receipts are less than $7,500,000. (13 CFR 121.201.)

Based on shipment data and other information provided by the Committee, most producers and approximately 13 handlers of California raisins may be classified as small entities. This action should not have any impact on handlers' or growers' benefits or costs.

There are approximately 52 raisins importers. This action should not have any impact on importers' costs.

This proposal would remove the word "midget" from the order regulations in § 989.702(a) and from the import regulations in § 999.300(b)(1), bringing the order and the import regulations into conformance with the recent amendment to the standards.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0178, "Vegetable and Specialty Crops." No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would not impose any additional reporting or recordkeeping requirements on either large or small raisin handlers or on raisin importers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. In addition, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this proposal.

Further, the Committee's meetings were widely publicized throughout the California raisin industry and all interested persons were invited to attend the meetings and encouraged to participate in Committee deliberations on all issues. Like all Committee meetings, the June 26, 2014, and August 14, 2014, meetings were public meetings and all entities, both large and small, were encouraged to express their views on this issue. Finally, interested persons are invited to submit comments on this proposed rule, including the regulatory and informational impacts of this action on small businesses.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *www.ams.usda.gov/MarketingOrdersSmallBusinessGuide.* Any questions about the compliance guide should be sent to Richard Lower at the previously-mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 30-day comment period is provided to allow interested persons to respond to this proposal. Thirty days is deemed appropriate because: (1) This proposed rule should be implemented as soon as possible since the standards have already been amended; (2) the Committee discussed this change at two public meetings, and unanimously recommended it; and (3) the proposed change is insignificant and should not impact handlers or importers. All written comments received during the comment period will be considered before a final determination is made on this matter.

List of Subjects

7 CFR Part 989

Grape, Marketing agreements, Raisins, Reporting and recordkeeping requirements.

7 CFR Part 999

Dates, Filberts, Food grades and standards, Imports, Nuts, Prunes, Raisins, Reporting and recordkeeping requirements, Walnuts.

For the reasons set forth in the preamble, 7 CFR parts 989 and 999 are proposed to be amended as follows:

PART 989—RAISINS PRODUCED FROM GRAPES GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 989 continues to read as follows:

Authority: 7 U.S.C. 601–674.

§ 989.702 Minimum grade standards for packed raisins.

■ 2. Paragraph (a) of § 989.702 is amended by removing the word "midget."

PART 999—SPECIALTY CROPS; IMPORT REGULATIONS

■ 3. The authority citation for 7 CFR part 999 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 4. Paragraph (b)(1) of § 999.300 is amended by removing the word "midget."

Dated: September 12, 2016.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2016–22270 Filed 9–15–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9139; Directorate Identifier 2016–CE–023–AD]

RIN 2120–AA64

Airworthiness Directives; Mitsubishi Heavy Industries, Ltd. Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Mitsubishi Heavy Industries, Ltd. Models MU–2B–10, MU–2B–15, MU–2B–20, MU–2B–25, MU–2B–26, MU–2B–26A, MU–2B–30, MU–2B–35, MU–2B–36, MU–2B–36A, MU–2B–40, and MU–2B–60 airplanes. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as reports of cracks found in the wing spacer plates. We are issuing this proposed AD to require actions to detect and correct cracks in the wing spacer plates, which could result in reduced structural integrity of the wings and loss of control.

DATES: We must receive comments on this proposed AD by October 31, 2016.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Mitsubishi Heavy Industries America, Inc., c/o Turbine Aircraft Services, Inc., 4550 Jimmy Doolittle Drive, Addison, Texas 75001; telephone: (972) 248–3108, ext. 209; fax: (972) 248–3321; Internet: *http://mu-2aircraft.com.* You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9139; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Andrew McAnaul, Aerospace Engineer, FAA, ASW–143 (c/o San Antonio MIDO), 10100 Reunion Place, Suite 650, San Antonio, Texas 78216; phone: (210) 308–3365; fax: (210) 308–3370; email: *andrew.mcanaul@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–9139; Directorate Identifier 2016–CE–023–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The Japan Civil Aviation Bureau (JCAB), which is the aviation authority for Japan, has issued AD No. TCD–8783–2016, dated June 28, 2016 (referred to after this as "the MCAI"), to correct an unsafe condition for certain Mitsubishi Heavy Industries, Ltd. (MHI) Models MU–2B–20, MU–2B–25, MU–2B–26, MU–2B–30, MU–2B–35, and MU–2B–36, airplanes. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2016–9139.

As part of the MHI MU–2B aging aircraft program, one-piece and three-piece main wings were subjected to detailed teardown inspections, and cracks were found in the wing spacer plates attached to the forward lower spar area at wing station 580. It was determined that the cracks resulted from fatigue caused by flight loads.

Japan is the State of Design for MHI Models MU–2B–20, MU–2B–25, MU–2B–26, MU–2B–30, MU–2B–35, and MU–2B–36 airplanes, which the MCAI AD applies to, and the United States is the State of Design for MHI Models MU–2B–26A, MU–2B–36A, MU–2B–40, and MU–2B–60 airplanes.

Related Service Information Under 1 CFR Part 51

Mitsubishi Heavy Industries, Ltd. has issued MU–2 Service Bulletin No. 245, dated April 21, 2016, and MU–2 Service Bulletin No. 107/57–005, dated May 3, 2016. These service bulletins describe procedures for doing a fluorescent penetrant inspection of the wing spacer plates for cracks and replacing cracked wing spacer plates with an improved part. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

FAA's Determination and Requirements of This Proposed AD

The Models MU–2B–20, MU–2B–25, MU–2B–26, MU–2B–30, MU–2B–35, and MU–2B–36 airplanes have been approved by the aviation authority of another country, and are approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

The procedures described in this proposed AD meet the FAA's expectations for flight with known cracks described in Chapter 6 in FAA Advisory Circular (AC) 23–13A Fatigue, Fail-Safe and Damage Tolerance Evaluation of Metallic Structure for Normal, Utility, Acrobatic, and Commuter Category Airplanes.

In addition, we are including the Models MU–2B–26A, MU–2B–36A, MU–2B–40, and MU–2B–60 airplanes for which the United States is the State of Design and the unsafe condition exists and is likely to exist or develop in other products of the same type design.

The Models MU–2B–10 and MU–2B–15 are not included in Japan Civil Aviation Bureau (JCAB) AD No. TCD–8783–2016, dated June 28, 2016, or any of the service bulletins referenced in this proposed AD. The FAA does not believe there are any of these airplanes currently in operation, but are including them as a part of this proposed AD.

Costs of Compliance

We estimate that this proposed AD will affect 209 products of U.S. registry. We also estimate that it would take about 8 work-hours per product to comply with the fluorescent penetrant inspection requirement of this proposed AD. The average labor rate is $85 per work-hour.

Based on these figures, we estimate the cost of the fluorescent penetrant inspection requirement of this proposed AD on U.S. operators to be $142,120, or $680 per product.

In addition, we estimate the following to do any necessary follow-on actions:

It would take about 200 work-hours and require parts costing $500, for a cost of $17,500, per product to replace a cracked wing spacer plate on one side of the airplane.

It would take about 250 work-hours and require parts costing $1,000, for a cost of $22,250, per product to replace a cracked wing spacer plate on both sides of the airplane.

We have no way of determining the number of products that may need this action.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

Mitsubishi Heavy Industries, Ltd.: Docket No. FAA–2016–9139; Directorate Identifier 2016–CE–023–AD.

(a) Comments Due Date

We must receive comments by October 31, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the following Mitsubishi Heavy Industries, Ltd. (MHI) models airplanes that are certificated in any category:

(1) MU–2B–10 and MU–2B–15: Serial Numbers (S/Ns) 101 and 103 through 120.

Note 1 to paragraph (c)(1) of this AD: The Models MU–2B–10 and MU–2B–15 are not included in Japan Civil Aviation Bureau (JCAB) AD No. TCD–8783–2016, dated June 28, 2016, or any of the service bulletins referenced in this AD. The FAA does not believe there are any of these airplanes currently in operation, but are including them as a part of this AD.

(2) MU–2B–20, MU–2B–25, and MU–2B–26: S/Ns 102 and 121 through 347, except 313 and 321;

(3) MU–2B–25, MU–2B–26, MU–2B–26A, and MU–2B–40: S/Ns 313SA, 321SA, and 348SA through 459SA;

(4) MU–2B–30, MU–2B–35, and MU–2B–36: S/Ns 502 through 696, except 652 and 661; and

(5) MU–2B–36A and MU–2B–60 airplanes: S/Ns 661SA, and 697SA through 1569SA.

(d) Subject

Air Transport Association of America (ATA) Code 57: Wings.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as reports of cracks found in the wing spacer plates. We are issuing this AD to detect and correct cracks in the wing spacer plates, which could result in reduced structural integrity of the wings and loss of control.

(f) Compliance

Comply with paragraphs (g)(1) through (3) of this AD using the following service bulletins within the compliance times specified below, unless already done. The Models MU–2B–10 and MU–2B–15 currently do not have service bulletins associated with them. The FAA does not believe any of these airplanes are currently in operation. If they do become operational, an alternative method of compliance must be obtained to comply with this AD.

(1) For Models MU–2B–20, MU–2B–25, and MU–2B–26: S/Ns 102 and 121 through 347, except 313 and 321, and MU–2B–30, MU–2B–35, and MU–2B–36: S/Ns 502 through 696, except 652 and 661: Use Mitsubishi Heavy Industries, Ltd. (MHI) MU–2 Service Bulletin No. 245, dated April 21, 2016.

(2) Models MU–2B–25, MU–2B–26, MU–2B–26A, and MU–2B–40: S/Ns 313SA, 321SA, and 348SA through 459SA, and MU–2B–36A and MU–2B–60 airplanes: S/Ns 661SA, and 697SA through 1569SA: Use MHI MU–2 Service Bulletin No. 107/57–005, dated May 3, 2016.

(g) Actions

(1) Do an initial fluorescent penetrant inspection of the wing spacer plates at whichever of the following compliance times that occurs later, and repetitively inspect thereafter at intervals not to exceed 2,000 hours time-in-service (TIS). Do the inspections following the Instructions section of the service bulletins identified in paragraph (f) of this AD, including all subparagraphs, as applicable.

(i) At or before accumulating 7,500 hours TIS; or

(ii) Within the next 200 hours TIS after the effective date of this AD or within the next 12 months after the effective date of this AD, whichever occurs first.

(2) During any inspection required in paragraph (g)(1) of this AD, including all subparagraphs, if any crack is found that is 0.6-inch or more in length, before further flight after the inspection in which the crack is found, replace the cracked wing spacer plate with an improved wing spacer plate, part number (P/N) 017A–11102–13 or 017A–11102–14. Do the replacement following the Instructions section of the service bulletins identified in paragraph (f) of this AD, including all subparagraphs, as applicable. Installing the improved wing spacer plates terminates the repetitive inspections required in paragraph (g)(1) of this AD.

(3) During any inspection required in paragraph (g)(1) of this AD, including all subparagraphs, if any crack is found that is less than 0.6-inch in length, repetitively fluorescent penetrant inspect for crack growth every 600 hours TIS after the inspection in which the crack was found. Do the inspections following the Instructions section of the service bulletins identified in paragraph (f) of this AD, including all subparagraphs, as applicable. If it is found during any required inspection that the crack has grown to0.6-inch in length or more, before further flight, replace the wing spacer plate as specified in paragraph (g)(2) of this AD.

(4) Installing improved wing spacer plates, part number (P/N) 017A–11102–13 or 017A–11102–14, terminates the repetitive inspections required in paragraph (g)(1) of this AD. You may install the improved wing spacer plates at any time to terminate the repetitive inspection requirement of this AD.

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Andrew McAnaul, Aerospace Engineer, FAA, ASW–143 (c/o San Antonio MIDO), 10100 Reunion Place, Suite 650, San Antonio, Texas 78216; phone: (210) 308–3365; fax: (210) 308–3370; email: *andrew.mcanaul@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(i) Related Information

Refer to MCAI JCAB AD No. TCD–8783–2016, dated June 28, 2016, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9139. For service information related to this AD, contact Mitsubishi Heavy Industries America, Inc., c/o Turbine Aircraft Services, Inc., 4550 Jimmy Doolittle Drive, Addison, Texas 75001; telephone: (972) 248–3108, ext. 209; fax: (972) 248–3321; Internet: *http://mu-2aircraft.com.* Youmay review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on September 8, 2016.

Pat Mullen,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–22182 Filed 9–15–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2016–C–2570]

McCormick & Company, Inc.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by McCormick & Company, Inc., proposing that the color additive regulations be amended to provide for the safe use of spirulina extract to color shell eggs at levels consistent with good manufacturing practice.

DATES: The color additive petition was filed on August 24, 2016.

FOR FURTHER INFORMATION CONTACT: Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1282.

SUPPLEMENTARY INFORMATION: Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 6C0306), submitted by McCormick & Company, Inc., c/o Exponent, 1150 Connecticut Ave. NW., Suite 1100, Washington, DC 20036. The petition proposes to amend the color additive regulations in § 73.530 (21 CFR 73.530) *Spirulina extract* to provide for the safe use of spirulina extract prepared by a water extraction and filtration of the dried biomass of *Arthrospira platensis* to color shell eggs.

We have determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: September 13, 2016.

Dennis M. Keefe,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 2016–22289 Filed 9–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0327]

RIN 1625–AA87

Security Zones; Port of Palm Beach, Port Everglades, Miami, and Key West, Florida

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to update and modify security zones in the Port of Palm Beach, Port Everglades, Port of Miami, and the Port of Key West, Florida. The revisions create a new section for the Sector Key West security zones that previously were annotated as belonging to Sector Miami; clarify when the Port Everglades fixed security zones will be in effect; modify and lengthen a portion of the Port Everglades fixed security zone; and update language and definitions throughout the regulation. The proposed amendments are largely administrative in nature, but the clarification of terms and geographic application of security zones between Sector Key West and Sector Miami ports will allow for more effective implementation of these regulations to protect the public and ports from potential subversive acts.

DATES: Comments and related material must be received by the Coast Guard on or before November 15, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0327 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Lieutenant Ruth Sadowitz, Sector Miami Waterways Management Division, U.S. Coast Guard; telephone (305) 535–4307, email *Ruth.A.Sadowitz@uscg.mil;* or BMC Jason Herbert, Sector Key West Waterways Management Division, U.S. Coast Guard; telephone (305) 292–8772, email *Jason.D.Herbert@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of proposed rulemaking
Pub. L.	Public Law
§	Section
U.S.C.	United States Code

II. Background, Purpose, and Legal Basis

On January 23, 2003, Captain of the Port Miami published a final rule entitled "Security Zones; Port of Palm Beach, Port Everglades, Port of Miami, and Port of Key West, Florida" in the **Federal Register** (68 FR 3189) to protect the public, ports, and waterways of the United States against potential subversive acts. Since the implementation of that rule, Sector Key West was delegated separate Captain of the Port authority (69 FR 47168) and the demands of commercial vessels in Sector Miami ports call for amendments to the standing security zone regulations.

The purpose of these proposed amendments is to protect the public and Ports from potential subversive acts. The amendments establish separate regulatory authority for Sector Key West, clarify when the Port Everglades fixed security zones will be in effect, modify and lengthen a portion of one of the Port Everglades fixed security zones, and update language throughout the regulation.

The legal basis for the proposed amendments is the Coast Guard's authority to establish regulated navigation areas and other limited access areas: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

III. Discussion of Proposed Rule

The fixed security zone from Mid-Port to North-Port (Pier 7 to the northern-most section of the Port) including all waters westward at Port Everglades would be an established permanent fixed security zone that will be in effect at all times. Berthing from Pier 7 to North-Port Port Everglades regularly serves passenger vessels, vessels carrying cargoes of particular hazards, and vessels carrying liquefied hazardous gas. This permanent fixed security zone, which parallels the Intracoastal Waterway, would not limit persons or vessels from using the main entrance channel (Bar Cut) or from using the

Intracoastal Waterway. This zone also would not restrict persons and vessels authorized to be in the zone from maneuvering around the berths within Port Everglades between Mid-Port and North-Port. This amendment clarifies that all persons and vessels not authorized to be in the zone shall remain out of the zone in order to protect the public and Port from potential subversive acts.

The fixed security zone that runs from Mid-Port south to Berth 29, just south of the John U. Lloyd launching ramps, along Port Everglades and the Intracoastal Waterway, would decrease in size to encompass only the waters westward of the Intracoastal Waterway extending to and including the pier face of Port Everglades. The fixed security zone would also lengthen southward from Berth 29, just south of the John U. Lloyd launching ramps to the northern tip of the Dania Cut-Off Canal. Persons and vessels would be allowed to operate along the Intracoastal Waterway, as they are now; however, persons and vessels would not be authorized to enter the security zone westward of the Intracoastal Waterway between Mid-Port and the northern tip of the Dania Cut-Off Canal without authorization. When a passenger vessel, vessel carrying cargoes of particular hazards, or vessel carrying liquefied hazardous gas moors along this section of Port Everglades, vessels transiting along the Intracoastal Waterway would be required to transit eastward of law enforcement vessels. This extension is needed to provide continuous protection for the public and Port because Port Everglades has expanded the entrance of the Dania Cut-Off Canal and its operations south over the years.

The term "cruise ship tenders" would be removed from the entire regulation because cruise ship tenders no longer provide security zone assistance.

The term "cruise ship" would be removed and "passenger vessels" will be redefined. Also, a "vessel carrying cargoes of particular hazards" and a "vessel carrying liquefied hazardous gas" will be defined.

As discussed above, since the implementation of Sector Miami security zones in 2003, Sector Key West was delegated its own Captain of the Port authority. Therefore, a separate section would be implemented by this proposed regulation to establish the security zone authority for Sector Key West.

These amendments are necessary for administrative reasons as noted above and to protect the public and Ports from potential subversive acts.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This NPRM has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget.

The economic impact of this proposed updates and modifications to the rule is not significant for the following reasons: (1) Persons and vessels would still be able to operate in waters surrounding the proposed security zones; (2) the permanent fixed security zone encompassing Port Everglades from Mid-Port to North-Port is within the natural boundaries of the Port and is limited in size; (3) notification of the security zones will be made to the local maritime community via posted signs and Broadcast Notice to Mariners when applicable; and (4) persons and vessels may operate within the security zone if authorized by Captain of the Port of Miami or a designated representative.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

The proposed amendments may affect the following entities, some of which may be small entities: People and the owners or operators of vessels intending to transit or remain within the security zone(s) when they are in effect. For reasons discussed in the Regulatory Planning and Review section above, these proposed amendments would not have a significant economic impact on a substantial number of small entities.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves amending security zones and lengthening part of a security zone. Normally such actions are categorically excluded from further review under paragraph 34(g) of Figure 2–1 of Commandant Instruction M16475.lD. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov*. If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 2. Add § 165.760 to read as follows:

§ 165.760 Security Zones; Port of Palm Beach, Port Everglades, and Port of Miami, Florida.

(a) *Definition.* (1) As used in this section, passenger vessel is a vessel greater than 100 feet in length and over 100 gross tons that is authorized to carry more than 12 passengers for hire making voyages lasting more than 24 hours, except for a ferry.

(2) As used in this section, a vessel carrying cargoes of particular hazard is defined in 33 CFR part 126 and a vessel carrying liquefied hazardous gas is defined in 33 CFR part 127.

(b) Location. The following areas are security zones. All coordinates are North American Datum 1983.

(1) *Fixed and moving security zones around vessels in the Port of Palm Beach, Port Everglades, and Port of Miami Florida.* Moving security zones are established 100 yards around all passenger vessels, vessels carrying cargoes of particular hazard, or vessels carrying liquefied hazardous gas (LHG) during transits entering or departing the Port of Palm Beach, Port Everglades, or Port of Miami. These moving security zones are activated when the subject vessel passes: Lake Worth Lighted Buoy LW at approximate position 26°46.3′ N., 80°00.6′ W. when entering the Port of Palm Beach; Port Everglades Lighted Buoy PE at approximate position 26°05.5′ N., 080°04.8′ W. when entering Port Everglades; and Miami Lighted Buoy M at approximate position 25°46.1′ N., 080°05.0′ W. when entering Port of Miami. These moving security zones remain active whenever a passenger vessel, vessels carrying cargoes of particular hazard, or vessels carrying LHG is underway westward of the above mentioned buoys. Fixed security zones are established 100 yards around all passenger vessels, vessels carrying cargoes of particular hazard, or vessels carrying LHG, while the vessel is moored in the Port of Palm Beach, Port Everglades, or Port of Miami, Florida. Persons and vessels may pass within 100 yards of a moored passenger vessel, vessel carrying cargoes of particular hazard, or vessel carrying LHG that is moored within or alongside a federal channel as long as the passage occurs outside of the on scene law enforcement vessel. Persons and vessels shall pass north of the on scene law enforcement vessel when north of the Port of Miami, north of the on scene law enforcement vessel when south of the Port of Miami, and east of the on scene law enforcement vessel in Port Everglades.

(2) *Fixed security zone in Port of Miami, Florida.* A fixed security zone encompasses all waters between Watson Park and Star Island from the MacArthur Causeway south to the Port of Miami. The western boundary is formed by an imaginary line from points 25°46.763′ N., 080°10.877′ W., northwest to 25°46.774′ N., 080°10.904′ W, northeast to 25°46.885′ N., 080°10.845′ W., and extending northeast ending at Watson Island at 25°47.001′ N., 080°10.670′ W. The eastern boundary is formed by an imaginary line approximately 100 yards west of the Fisher Island Ferry terminal, in approximate position 25°46.330′ N., 080°09.120′ W., extending southwest across the Main Channel to Port of Miami, at 25°46.247′ N., 080°09.191′ W.

The fixed security zone is in effect when two or more passenger vessels, vessels carrying cargoes of particular hazard, or vessels carrying LHG, enter or moor within this zone.

(i) When the security zone is in effect, persons and vessels shall not enter or transit the security zone along the Miami Main Channel unless authorized by Captain of the Port of Miami or a designated representative.

(ii) Persons and vessels may transit the Miami Main Channel when only one passenger vessel, one vessel carrying cargoes of particular hazard, or one vessel carrying LHG is berthed.

(iii) Law enforcement vessels can be contacted on VHF Marine Band Radio, Channel 16 (156.8 MHz).

(3) *Fixed security zones in Port Everglades.* A fixed security zone encompasses Mid-Port to North-Port in Port Everglades and includes all waters west of an imaginary line starting at the southernmost point 26°05.410′ N., 080°06.960′ W., on the northern tip of berth 22, to the northernmost point 26°05.982′ N., 080°07.153′ W., near the west side of the 17th Street Bridge. An additional fixed security zone encompasses the waters west of the Intracoastal Waterway to the pier face of Port Everglades from Mid-Port south to the northern tip of the Dania Cut-Off Canal and includes the waters westward of the line connecting the following points to the pier face of Port Everglades: Starting at 26°05.411′ N., 080°06.960′ W., on the northern tip of Berth 23 at Mid-Port, to a point directly east along the Intracoastal Waterway, 26°05.411′ N., 080°06.920′ W., then southeast along the Intracoastal Waterway to 26°05.242′ N., 080°06.859′ W., then southeast along the Intracoastal Waterway to 26°05.157′ N., 080°06.846′ W., then southwest along the Intracoastal Waterway to 26°03.906′ N., 080°06.874′ W., and then west to the Port Everglades pier face just north of the Dania Cut-Off Canal at 26°03.906′ N., 080°06.922′ W.

(i) Persons and vessels may transit the Intracoastal Waterway; however, persons and vessels are not authorized to enter the fixed security zone westward of the Intracoastal Waterway without authorization from Captain of the Port Miami or a designated representative. On occasion, a passenger vessel, vessel carrying cargoes of particular hazard, or vessel carrying LHG may moor and encroach into the Intracoastal Waterway. When this occurs, persons and vessels shall transit the Intracoastal Waterway east of the on scene law enforcement vessel.

(ii) Periodically, vessels may be required to temporarily hold their positions while large commercial traffic operates in this area. Vessels near the security zone must follow the orders of the Captain of the Port or the designated representative.

(iii) Law enforcement vessels can be contacted on VHF Marine Band Radio, Channel 16 (156.8 MHz).

(c) *Regulations.* (1) Prior to commencing any movement, the person directing the movement of a passenger vessel, a vessel carrying cargoes of particular hazard, or a vessel carrying liquefied hazardous gas, is encouraged to make a security broadcast on VHF Marine Band Radio, Channel 13 (156.65 MHz) to advise mariners of the moving security zone activation and intended transit.

(2) In accordance with the general regulations § 165.33 of this part, entry into these zones is prohibited except as authorized by the Captain of the Port Miami or a designated representative. Vessels such as pilot boats, tug boats, and contracted security vessels may assist the Coast Guard Captain of the Port by monitoring these zones strictly to advise mariners of the restrictions. The Captain of the Port will notify the public of the security zone via signs or by Marine Safety Radio Broadcasts on VHF Marine Band Radio, Channel 16 (156.8 MHz) when applicable.

(3) Persons and vessels desiring to enter or transit the fixed or moving security zones may contact the Captain of the Port Miami at (305) 535–4472 or on VHF Marine Band Radio, Channel 16 (156.8 MHz) to seek permission to transit the area. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port or the designated representative.

(4) The Captain of the Port Miami may waive any of the requirements of this subpart for any vessel upon finding that the vessel or class of vessel, operational conditions, or other circumstances are such that application of this subpart is unnecessary or impractical for the purpose of port security, safety, or environmental safety.

■ 3. Revise § 165.761 to read as follows:

§ 165.761 Security Zones; Port of Key West, Florida.

(a) *Definition.* (1) As used in this section, passenger vessel is a vessel greater than 100 feet in length and over 100 gross tons that is authorized to carry more than 12 passengers for hire making voyages lasting more than 24 hours, except for a ferry.

(2) As used in this section, a vessel carrying cargoes of particular hazard is defined in 33 CFR part 126 and a vessel carrying liquefied hazardous gas is defined in 33 CFR part 127.

(b) *Location.* Fixed and moving security zones around vessels in the Port of Key West, Florida. A moving security zones is established 100 yards around all passenger vessels, vessels carrying cargoes of particular hazard, or vessels carrying liquefied hazardous gas (LHG) during transits entering or departing the Port of Key West, Florida. A moving security zone is activated when the subject vessel passes Key West Lighted Buoy KW, at approximate position 24°27.7′ N., 081°48.1′ W. This moving security zone remains active whenever a passenger vessel, vessels carrying cargoes of particular hazard, or vessels carrying LHG is underway westward of the above mentioned buoys. Fixed security zones are established 100 yards around all passenger vessels, vessels carrying cargoes of particular hazard, or vessels carrying LHG, while the vessel is moored in the Port of Key West, Florida.

(c) *Regulations.* (1) Prior to commencing any movement, the person directing the movement of a passenger vessel, a vessel carrying cargoes of particular hazard, or a vessel carrying LHG, is encouraged to make a security broadcast on VHF Marine Band Radio, Channel 13 (156.65 MHz) to advise mariners of the moving security zone activation and intended transit.

(2) In accordance with the general regulations § 165.33 of this part, entry into these zones is prohibited except as authorized by the Captain of the Port Key West or a designated representative. Vessels such as pilot boats, tug boats, and contracted security vessels may assist the Coast Guard Captain of the Port by monitoring these zones and advising mariners of the restrictions. The Captain of the Port will notify the public of the security zone via signs or by Marine Safety Radio Broadcasts on VHF Marine Band Radio, Channel 16 (156.8 MHz) when applicable.

(3) Persons and vessels desiring to enter or transit the fixed or moving security zones may contact the Captain of the Port Key West at (305) 292–8727 or on VHF Marine Band Radio, Channel 16 (156.8 MHz) to seek permission to transit the area. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port or the designated representative.

(4) The Captain of the Port Key West may waive any of the requirements of this subpart for any vessel upon finding that the vessel or class of vessel, operational conditions, or other circumstances are such that application of this subpart is unnecessary or

impractical for the purpose of port security, safety, or environmental safety.

Dated: September 12, 2016.

A.J. Gould,

Captain, U.S. Coast Guard, Acting Commander, Seventh Coast Guard District.

[FR Doc. 2016–22280 Filed 9–15–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2016–0444; FRL–9952–48–Region 9]

Approval of California Air Plan Revisions, South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the South Coast Air Quality Management District (SCAQMD) portion of the California State Implementation Plan (SIP). These revisions concern emissions of oxides of nitrogen (NO_X) from ovens, dryers, dehydrators, heaters, kilns, calciners, furnaces, crematories, incinerators, heated pots, cookers, roasters, smokers, fryers, closed and open heated tanks and evaporators, distillation units, afterburners, degassing units, vapor incinerators, catalytic or thermal oxidizers, soil and water remediation units, and other combustion equipment. We are proposing to approve local rules to regulate these emission sources under the Clean Air Act (CAA or the Act). We are taking comments on this proposal and plan to follow with a final action.

DATES: Any comments must arrive by October 17, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2016–0444 at *http://www.regulations.gov,* or via email to Andrew Steckel, Rulemaking Office Chief at *steckel.andrew@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be removed or edited from *Regulations.gov.* For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the Web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Nicole Law, EPA Region IX, (415) 947–4126, *law.nicole@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, "we," "us" and "our" refer to the EPA.

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I. The State's Submittal

A. What rules did the State submit?

Table 1 lists the rules addressed by this action with the dates that they were adopted by the local air agency and submitted by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED RULES

Local agency	Rule #	Rule title	Adopted/ amended	Submitted
SCAQMD	1147	NO_X Reductions from Miscellaneous Sources	09/09/2011	02/06/2013
SCAQMD	1153.1	Emissions of Oxides of Nitrogen from Commercial Food Ovens	09/07/2014	04/07/2015

On April 9, 2013 and April 30, 2015, the EPA determined that the submittals for SCAQMD Rule 1147 and SCAQMD Rule 1153.1 met the completeness criteria in 40 CFR part 51 Appendix V, which must be met before formal EPA review.

B. Are there other versions of these rules?

There are no previous versions of Rule 1153.1. We approved an earlier version of Rule 1147 into the SIP on August 4, 2010 (75 FR 46845).

C. What is the purpose of the submitted rules and rule revisions?

NO_X helps produce ground-level ozone, smog and PM, which harm human health and the environment. Section 110(a) of the CAA requires States to submit regulations that control NO_X emissions. The revisions made to SCAQMD Rule 1147 are administrative amendments that delay compliance dates. SCAQMD Rule 1153.1 is a new rule that carves out the category of commercial food ovens from Rule 1147. Rule 1153.1 delays compliance and contains different NO_X emission limits than were required under rule 1147. The EPA's technical support documents (TSDs) have more information about these rules.

II. The EPA's Evaluation and Action

A. How is the EPA evaluating the rules?

SIP rules must be enforceable (see CAA section 110(a)(2)), must not interfere with applicable requirements concerning attainment and reasonable further progress or other CAA requirements (see CAA section 110(l)), and must not modify certain SIP control requirements in nonattainment areas without ensuring equivalent or greater emissions reductions (see CAA section 193).

Generally, SIP rules must require Reasonably Available Control Technology (RACT) for each major source of NO_X in ozone nonattainment areas classified as moderate or above (see CAA sections 182(b)(2) and 182(f)). The SCAQMD regulates an ozone nonattainment area classified as extreme for the 1-hour ozone standard, the 8-hour 1997 ozone standard, and the 8-hour 2008 ozone standard (40 CFR

81.305). Therefore, these rules must implement RACT. Additionally, SIP rules must implement Best Available Control Measures (BACM), including Best Available Control Technology (BACT), in serious $PM_{2.5}$ nonattainment areas (see CAA section 189(b)(1)(B)). The SCAQMD regulates a $PM_{2.5}$ nonattainment area classified as serious for the 2006 24-hr $PM_{2.5}$ standard. (40 CFR 81.305.) Therefore, although these rules must implement BACM and BACT, the BACM and BACT evaluation is generally performed in context of a broader plan and is not part of this rule evaluation.

Guidance and policy documents that we use to evaluate enforceability, revision/relaxation and rule stringency requirements for the applicable criteria pollutants include the following:

1. "State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990," 57 FR 13498 (April 16, 1992); 57 FR 18070 (April 28, 1992).
2. "Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations," EPA, May 25, 1988 (the Bluebook, revised January 11, 1990).
3. "Guidance Document for Correcting Common VOC & Other Rule Deficiencies," EPA Region 9, August 21, 2001 (the Little Bluebook).
4. "State Implementation Plans; Nitrogen Oxides Supplement to the General Preamble; Clean Air Act Amendments of 1990 Implementation of Title I; Proposed Rule," (the NO_X Supplement), 57 FR 55620, November 25, 1992.
5. "NO_X Emissions from Industrial/Commercial/Institutional (ICI) Boilers," EPA, March 1994, (EPA–453/R–94–022, March 1994).
6. "Determination of Reasonably Available Control Technology and Best Available Retrofit Control Technology for Industrial, Institutional, and Commercial Boilers, Steam Generators, and Process Heaters," CARB, July 18, 1991.

B. Do the rules meet the evaluation criteria?

We believe these rules are consistent with CAA requirements and relevant guidance regarding enforceability, RACT and SIP revisions. SCAQMD previously adopted stringent future-effective emission limits that had not been widely implemented for all affected sources. SCAQMD intended to encourage wider adoption of low-emitting technology, but understood that some sources might not be able to comply on schedule for these and similar future-effective limits in other rules. As a result, SCAQMD did not take credit for ("set aside") some emission reductions in certain attainment demonstrations. SCAQMD subsequently determined that some sources cannot comply with Rules 1147 and 1153.1 on schedule despite reasonable efforts and therefore delayed certain compliance dates. We do not believe that these changes impact the 2015 impracticability demonstration for the 2006 NAAQS for $PM_{2.5}$, the 2022 attainment demonstration for 1-hour ozone, or the 2023 attainment demonstration for the 1997 8-hour ozone standard because the forgone emission reductions are less than a one ton per day set aside by SCAQMD in their 2014 inventory used to model attainment and beyond 2020 there are no emissions forgone due to the rule amendments. The TSDs have more information on our evaluation.

C. EPA Recommendations to Further Improve the Rules

The TSDs describe additional rule revisions that we recommend for the next time the local agency modifies the rules but are not currently the basis for rule disapproval.

D. Public Comment and Proposed Action

As authorized in section 110(k)(3) of the Act, the EPA proposes to fully approve the submitted rules because we believe they fulfill all relevant requirements. We will accept comments from the public on this proposal until October 17, 2016. If we take final action to approve the submitted rules, our final action will incorporate these rules into the federally enforceable SIP.

III. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the SCAQMD rules described in Table 1 of this preamble. The EPA has made, and will continue to make, these materials available through *www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely proposes to approve State law as meeting federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: August 24, 2016.

Alexis Strauss,

Acting Regional Administrator, Region IX.

[FR Doc. 2016–22388 Filed 9–15–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2016–0473; FRL–9952–29–Region 4]

Air Plan Approval; Alabama: Volatile Organic Compounds

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a portion of a revision to the Alabama State Implementation Plan submitted by the Alabama Department of Environmental Management on May 8, 2013. The revision modifies the definition of "volatile organic compounds" (VOC). Specifically, the revision adds one compound to the list of those excluded from the VOC definition on the basis that this compound makes a negligible contribution to tropospheric ozone formation. This action is being taken pursuant to the Clean Air Act.

DATES: Written comments must be received on or before October 17, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2016–0473 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Sean Lakeman, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Mr. Lakeman can be reached by phone at (404) 562–9043 or via electronic mail at *lakeman.sean@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Rules and Regulations section of this **Federal Register**, EPA is approving the State's implementation plan revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

Dated: September 2, 2016.

V. Anne Heard,

Acting Regional Administrator, Region 4.

[FR Doc. 2016–22218 Filed 9–15–16; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 81, No. 180

Friday, September 16, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0047]

Pale Cyst Nematode; Update of Quarantined Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that we have made changes to the areas in the State of Idaho that are quarantined to prevent the spread of pale cyst nematode. The description of the quarantined area has been updated several times since the last notice was published on September 8, 2010.

FOR FURTHER INFORMATION CONTACT: Mr. Jonathan M. Jones, National Program Manager, Emergency and Domestic Programs, PPQ, 4700 River Road, Unit 160, Riverdale, MD 20737; (301) 851–2128.

SUPPLEMENTARY INFORMATION: The pale cyst nematode (PCN, *Globodera pallida*) is a major pest of potato crops in cool-temperature areas. Other solanaceous hosts include tomatoes, eggplants, peppers, tomatillos, and some weeds. The PCN is thought to have originated in Peru and is now widely distributed in many potato-growing regions of the world. PCN infestations may be expressed as patches of poor growth. Affected potato plants may exhibit yellowing, wilting, or death of foliage. Even with only minor symptoms on the foliage, potato tuber size can be affected. Unmanaged infestations can cause potato yield loss ranging from 20 to 70 percent. The spread of this pest in the United States could result in a loss of domestic or foreign markets for U.S. potatoes and other commodities.

In 7 CFR part 301, the PCN quarantine regulations (§§ 301.86 through 301.86–9, referred to below as the regulations) set out procedures for determining the areas quarantined for PCN and impose restrictions on the interstate movement of regulated articles from quarantined areas.

Section 301.86–3 of the regulations sets out the procedures for determining the areas quarantined for PCN. Paragraph (a) of § 301.86–3 states that, in accordance with the criteria listed in § 301.86–3(c), the Administrator will designate as a quarantined area each field that has been found to be infested with PCN, each field that has been found to be associated with an infested field, and any area that the Administrator considers necessary to quarantine because of its inseparability for quarantine enforcement purposes from infested or associated fields.

Paragraph (d) provides for the removal of fields from quarantine. An infested field will be removed from quarantine when a protocol approved by the Administrator as sufficient to support the removal of infested fields from quarantine has been completed and the field has been found to be free of PCN. An associated field will be removed from quarantine when the field has been found to be free of PCN according to a protocol approved by the Administrator as sufficient to support removal of associated fields from quarantine. Any area other than infested or associated fields that has been quarantined by the Administrator because of its inseparability for quarantine enforcement purposes from infested or associated fields will be removed from quarantine when the relevant infested or associated fields are removed from quarantine.

Paragraph (a) of § 301.86–3 further provides that the Administrator will publish a description of the quarantined area on the Plant Protection and Quarantine (PPQ) Web site. The description of the quarantined area will include the date the description was last updated and a description of the changes that have been made to the quarantined area. The description of the quarantined area may also be obtained by request from any local office of PPQ; local offices are listed in telephone directories. Finally, paragraph (a) establishes that, after a change is made to the quarantined area, we will publish a notice in the **Federal Register** informing the public that the change has occurred and describing the change to the quarantined area.

Therefore, we are publishing this notice to inform the public of changes to the PCN quarantined areas in Bonneville and Bingham Counties in the State of Idaho. The changes are as follows:

- In 2011, we added 15,044 acres and removed 667 acres, resulting in 14,641 acres regulated, of which 1,467 acres were infested;
- In 2012, we added 4,356 acres and removed 5,363 acres, resulting in 14,740 acres regulated, of which 1,915 acres were infested;
- In 2013, we added 688 acres and removed 4,651 acres, resulting in 10,774 acres regulated, of which 2,300 acres were infested;
- In 2014, we added 1,315 acres and removed 2,094 acres, resulting in 7,734 acres regulated of which 2,897 acres were infested; and
- In 2015, we added 2,586 acres and removed 321 acres, resulting in 9,999 acres regulated, of which 2,897 acres were infested.

The current map of the quarantined area can be viewed on the PPQ Web site at *http://www.aphis.usda.gov/plant_health/plant_pest_info/potato/pcn.shtml.*

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 12th day of September 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016–22328 Filed 9–15–16; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0049]

Notice of Availability of a Treatment Evaluation Document; Cold Treatment of Grapefruit From Australia

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: We are advising the public that we have determined that it is warranted to amend cold treatment

schedule T107–d–3 in the Plant Protection and Quarantine Treatment Manual to extend the applicability of the treatment to grapefruit from Australia. We have prepared a treatment evaluation document that describes the amended treatment schedule and explains why we have determined that it is effective at neutralizing certain target pests. We are making this treatment evaluation document available to the public for review and comment.

DATES: We will consider all comments that we receive on or before November 15, 2016.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0049.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2016–0049, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0049* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Dorothy C. Wayson, Senior Regulatory Policy Specialist, Imports, Regulations and Manuals, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737–1231; (301) 851–2036.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR chapter III are intended, among other things, to prevent the introduction or dissemination of plant pests and noxious weeds into or within the United States. Under the regulations, certain plants, fruits, vegetables, and other articles must be treated before they may be moved into the United States or interstate. The phytosanitary treatments regulations contained in 7 CFR part 305 (referred to below as the regulations) set out standards for treatments required in 7 CFR parts 301, 318, and 319 for fruits, vegetables, and other articles.

In § 305.2, paragraph (b) states that approved treatment schedules are set out in the Plant Protection and Quarantine (PPQ) Treatment Manual.[1] Section 305.3 sets out the processes for adding, revising, or removing treatment schedules in the PPQ Treatment Manual. In that section, paragraph (a) sets out the normal process for adding, revising, or removing treatment schedules.

Currently, grapefruit is authorized for importation from Australia into the United States if it was produced in fruit fly free areas in Riverina, Riverland, or Sunraysia, or if the fruit has been subjected to cold treatment to mitigate the risks from Mediterranean fruit fly (Medfly, *Ceratitis capitata* (Wiedemann)) and Queensland fruit fly (*Bactrocera tryoni* (Froggatt)).

The cold treatment currently used, T107–d, requires fruit to be subject to refrigeration at or below 2.22 °C for up to 22 days with no option to treat at 3 °C. We are proposing to amend the treatment schedule T107–d–3 to add grapefruit to the schedule. With this change, exporters would have the option to have grapefruit cold-treated at up to 3 °C for no more than 14 days to meet U.S. entry requirements.

In March 2011, APHIS approved cold treatment at or below 3 °C for lemons, oranges, tangerines, and tangors from Australia to meet U.S. entry requirements.

PPQ's Center for Plant Health Science and Technology (CPHST) reviewed a research study conducted in New South Wales for Queensland fruit fly in grapefruit.

After the review, CPHST found that during the most tolerant stage testing (small scale), no insects were found alive after 10 days at either 2 °C or 3 °C and that the most tolerant life stage was determined to be the larval stage, first instar. Additionally, in the confirmatory stage testing (large scale), no insects were found alive after 14 days at either 2 °C or 3 °C.

We believe, therefore, that it is appropriate to amend T107–d–3 to add grapefruit from Australia.

The reasons for this change to the treatment manual are described in detail in the treatment evaluation document (TED) we have prepared to support this action. The TED may be viewed on the *Regulations.gov* Web site or in our reading room (see **ADDRESSES** above for instructions for accessing *Regulations.gov* and information on the location and hours of the reading room).

You may also request paper copies of the TED by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the subject of the TED when requesting copies.

After reviewing the comments we receive, we will announce our decision regarding the revised treatment schedule described in the TED in a subsequent notice, in accordance with paragraph (a)(2) of § 305.3. If we do not receive any comments, or the comments we receive do not change our determination that the proposed changes are effective, we will affirm these changes to the PPQ Treatment Manual and make available a new version of the PPQ Treatment Manual reflecting these changes. If we receive comments that cause us to determine that the changes described in this notice are not appropriate, we will issue another notice informing the public of our determination.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 12th day of September 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016–22327 Filed 9–15–16; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Economic Research Service

Notice of Intent To Request New Information Collection

AGENCY: Economic Research Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) implementing regulations, the U.S. Department of Agriculture Economic Research Service (ERS) invites the general public and other Federal agencies to take this opportunity to comment on a proposed new information collection for a study of "Risk Preferences and Demand for Crop Insurance and Cover Crop Programs."

DATES: Written comments on this notice must be received on or before November 15, 2016 to be assured of consideration.

ADDRESSES: Address all comments concerning this notice to Stephanie Rosch, Market and Trade Economics Division, Economic Research Service,

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[1] The PPQ Treatment Manual is available at *http://www.aphis.usda.gov/import_export/plants/manuals/index.shtml* or by contacting the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Manuals Unit, 92 Thomas Johnson Drive, Suite 200, Frederick, MD 21702.

U.S. Department of Agriculture, 1400 Independence Ave. SW., Mail Stop 1800, Washington, DC 20250–0002. Submit electronic comments to *stephanie.rosch@ers.usda.gov.*

All written comments will be open for public inspection at the office of the Economic Research Service during regular business hours (8:30 a.m. to 5:00 p.m., Monday through Friday) at 355 E St. SW., Room 5–149B, Washington, DC 20024–3221.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments and replies will be a matter of public record. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: For further information contact Stephanie Rosch at the mailing address in the preamble. Tel. 202–694–5049.

SUPPLEMENTARY INFORMATION:

Title: Risk Preferences and Demand for Crop Insurance and Cover Crop Programs.

OMB Number: To be assigned by OMB.

Expiration Date: Three years from approval date.

Type of Request: New information collection.

Abstract: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–12) and OMB regulations at 5 CFR part 1320 (60 FR 44978, August 29, 1995), this notice announces USDA Economic Research Services' intention to request approval from the Office of Management and Budget (OMB) for a new data collection effort. This data collection will use an experiment with university students to (1) characterize the relationship between cover crop usage and crop insurance purchases, and (2) explore how this relationship depends on individuals' risk preferences and demographic characteristics. Outputs from the proposed experiment will be used to inform future risk management experiments with farmer participants.

Commodity support programs, including crop insurance, and programs to promote use of cover crops all significantly alter the farm revenue risk profile for the farmers who adopt them. Whether farmers will choose to adopt insurance and/or soil conversation programs depends on the individual risks faced by each farmer, which can vary across different regions, crops, and time periods, as well as how farmers assess the costs of the risks that they face. ERS currently models the demand for commodity support programs, federal crop insurance, and cover crop promotion programs as part of multiple research objectives. These economic models rely on traditional theories of farmer decision-making under risk, and over-predict participation rates for all crop insurance and cover crop programs.

The information to be collected in this proposed initiative is necessary to test alternate theories of decision-making under risk. This research is difficult to conduct without experiments and relying only on observational or administrative data due to the variety of U.S. farms and production practices, the variety and complexity of real-world programs, and the limited variation in premium subsidies across the U.S. farming population. By using experiments, we will be able identify alternate theories of decision-making under risk that provide more accurate predictions of crop insurance enrollments for student subjects. We plan to use these experiments to develop future follow-on experiments with farmer subjects—the results of which will be used to update existing ERS models to provide better estimates of the impact of subsidies on key subpopulations such as producers with marginal lands and producers of high value crops.

This experiment will be conducted with student subjects from the University of Rhode Island. Participation will be voluntary, and subjects will be recruited using email communications and classroom solicitations. During each session, subjects will perform three simple tasks involving risky decisions and complete a brief demographic questionnaire. Sessions will be conducted at the Department of Environmental and Natural Resource Economics' Policy Simulation Laboratory (SimLab) at the University of Rhode Island. All experimental tasks will conducted using SimLab computers and custom-designed software.

Each session will last for a maximum of 90 minutes. Subjects will receive a show-up fee of $10 as is consistent with standard practice at SimLab. They will receive this payment even if they decline to participate in the experiment. In addition to the show-up fee, subjects will receive compensation based on the decisions they make during the course of the experiment. We expect to pay subjects, on average, between $20–25 per person, including the show-up fee. In designing our experimental procedures and payment levels, we took into consideration academic standards, statistical power considerations, budgetary limitations, and discussions between OMB and ERS regarding this and other approved experimental research.

Authority: These data will be collected under the legal authority of 7 U.S.C. 2204(a).

ERS intends to protect respondent information under the Privacy Act of 1974 and 7 U.S.C. 2276. ERS has decided not to invoke the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA). The complexity and cost necessary to invoke CIPSEA is not justified given the nature of the collection; the collection will be conducted by the University of Rhode Island and hosted in non-government owned computer systems, where CIPSEA compliance cannot be assured.

Affected Public: All respondents will be students at the University of Rhode Island.

Estimated Number of Respondents and Respondent Burden: Public reporting burden for this information collection of information is estimated to be 861 hours. We anticipate 750 burden hours will be needed to complete the experiment (500 subjects total, 1.5 hours per subject) and 111 burden hours for subject recruitment (2000 potential subjects, 2–5 minutes per potential subject).

Copies of this information collection can be obtained from Stephanie Rosch at the address in the preamble.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments should be sent to the address in the preamble. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Date: September 6, 2016.

Mary Bohman,

Administrator, Economic Research Service.

[FR Doc. 2016–22244 Filed 9–15–16; 8:45 am]

BILLING CODE 3410–18–P

DEPARTMENT OF AGRICULTURE

U.S. Forest Service

Nez Perce-Clearwater National Forests; Idaho; Johnson Bar Fire Salvage Project

AGENCY: Forest Service, USDA.

ACTION: Notice of Intent (NOI) to prepare a Supplemental Environmental Impact Statement (SEIS) for the Johnson Bar Fire Salvage Project.

SUMMARY: The U.S. Forest Service is giving notice of its intent to prepare a SEIS for the Johnson Bar Fire Salvage Project on the Nez Perce-Clearwater National Forests, Moose Creek Ranger District, Idaho. A complaint was filed on 11 March 2016 against the February 2016 Johnson Bar Salvage Record of Decision (ROD) and a Preliminary Injunction was granted by the United States District Court for the State of Idaho on 12 May 2016. This SEIS will provide additional analysis in response to the Preliminary Injunction.

FOR FURTHER INFORMATION CONTACT: Sheila D. Lehman, NEPA Planner/Interdisciplinary Team Leader, (208) 935–4256.

SUPPLEMENTARY INFORMATION: The U.S. Forest Service is announcing its intent to prepare a SEIS for the Johnson Bar Fire Salvage Project. The SEIS will supplement the analysis from the Johnson Bar Fire Salvage EIS by providing an updated analysis of the environmental effects. The Johnson Bar Fire Salvage Final EIS evaluated the potential effects of four alternatives, which included the No Action, Proposed Action, and two additional alternatives. The units possessing viable harvest potential will be carried forward for analysis in this SEIS.

The Nez Perce-Clearwater Forest Supervisor will issue a new ROD after evaluating the SEIS and public comments. An objection period for the new ROD will be provided, consistent with 36 CFR part 218.

Authority: This NOI is being published pursuant to regulations (40 CFR 1508.22) implementing the procedural provisions of the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 *et seq.*).

Scoping: A NOI published on 24 October 2014 initiated the scoping period for the Johnson Bar Salvage project. A legal notice advertising the start of a 30-day scoping period was advertised in the Lewiston, Idaho *Lewiston Tribune* on 29 October 2014. In accordance with 40 CFR 1502.9(c)(4), there will be no scoping conducted for this SEIS. The scope of the Final Johnson Bar Fire Salvage EIS and the Preliminary Injunction decision by the District Court of the Ninth Circuit establish the scope for this SEIS.

The SEIS will be advertised for public comment as required by 40 CFR 1503.1. The Draft SEIS will be announced for public review and comment in the **Federal Register**, on the Nez Perce-Clearwater National Forests' project Web site (*http://data.ecosystem-management.org/nepaweb/nepa_project_exp.php?project=45214*), and in the Lewiston, Idaho *Lewiston Tribune*, as well as other local media.

Responsible Official and Lead Agency

The USDA Forest Service is the lead agency for this proposal. The Nez Perce—Clearwater Forest Supervisor is the responsible official.

Decision to Be Made is whether to adopt the proposed action, in whole or in part, or another alternative; and what mitigation measures and management requirements will be implemented.

Dated: September 7, 2016.

Cheryl F. Probert,

Forest Supervisor.

[FR Doc. 2016–22318 Filed 9–15–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Rural Housing Service

Submission for OMB Review; Comment Request

September 12, 2016.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by October 17, 2016 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Housing Service

Title: 7 CFR 1956–C, Debt Settlement—Community and Business Programs.

OMB Control Number: 0575–0124.

Summary of Collection: The Community and Direct Business Programs loans and grants are authorized by the Consolidated Farm and Rural Development Act. Rural Housing Service (RHS) is a credit agency for agricultural and rural development for the United States Department of Agriculture and offers supervised credit to develop, improve and operate family farms, modest housing, essential community facilities, and business and industry across rural America. 7 CFR 1956–C, Debt Settlement—Community and Business Programs provides policies and procedures as well as a mechanism for debt settlement in connection with Community Facilities loans and grants, direct Business and Industry loans, Indian Tribal Land Acquisition loans and Irrigation and Drainage. The debt settlement program provides the delinquent client with an equitable tool for the compromise, adjustment, cancellation, or charge-off of a debt owed to the Agency.

Need and Use of the Information: The field offices will collect information from applicants, borrowers, consultants, lenders, and attorneys to determine eligibility, financial capacity and derive an equitable resolution. This information collected is similar to that required by a commercial lender in similar circumstances. Failure to collect the information could result in improper servicing of these loans.

Description of Respondents: Not for profit institutions; Business or other for-profit; State, Local or Tribal Government.

Number of Respondents: 35.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 1,041.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2016–22241 Filed 9–15–16; 8:45 am]

BILLING CODE 3410–XV–P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Maine Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of monthly planning meetings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a planning meeting of the Maine State Advisory Committee to the Commission will convene by conference call at 1:30 p.m. (EST) a planning meeting on the following dates: Tuesday, October 18, 2016; Tuesday, November 15, 2016; Tuesday, December 20, 2016; Tuesday, January, 17, 2017 and Tuesday, February 21, 2017. The purpose of each planning meeting is to discuss project planning as the Committee moves to selecting a topic as its civil rights project and once the project is selected to continue working on the project. The Committee may also select additional officers, as necessary.

DATES: The following dates: Tuesday, October 18, 2016; Tuesday, November 15, 2016; Tuesday, December 20, 2016; Tuesday, January, 17, 2017 and Tuesday, February 21, 2017. Each meeting starts at 1:30 p.m. (EST).

Public Call-in Information: Conference call number: 1–888–670–2260 and conference call ID: 3837382.

FOR FURTHER INFORMATION CONTACT: Ivy L. Davis, at *ero@usccr.gov* or by phone at 202–376–7533.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call number: 1–888–670–2260 and conference call ID: 3837382. Please be advised that before placing them into the conference call, the conference call operator will ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number herein.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1–888–364–3109 and providing the operator with the toll-free conference call number: 1–888–670–2260 and conference call ID: 3837382.

Members of the public are invited to submit written comments; the comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, faxed to (202) 376–7548, or emailed to Evelyn Bohor at *ero@usccr.gov.* Persons who desire additional information may contact the Eastern Regional Office at (202) 376–7533.

Records and documents discussed during the meeting will be available for public viewing as they become available at *https://database.faca.gov/committee/meetings.aspx?cid=252;* click the "Meeting Details" and "Documents" links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meetings. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone number, email or street address.

Agenda

I. Welcome
  Rollcall
II. Planning Meeting
  Discuss project planning.
III. Other Business
IV. Adjournment

Dated: September 13, 2016.

David Mussatt,

Chief, Regional Programs Unit.

[FR Doc. 2016–22334 Filed 9–15–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE884

Mid-Atlantic Fishery Management Council (MAFMC); Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold public meetings of the Council and its Committees.

DATES: The meetings will be held Tuesday, October 4, 2016 through Thursday, October 6, 2016. For agenda details, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: The meeting will be held at: Stockton Seaview Hotel, 401 South New York Road, Galloway, NJ 08205, telephone: (609) 652–1800.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State St., Suite 201, Dover, DE 19901; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D. Executive Director, Mid-Atlantic Fishery Management Council; telephone: (302) 526–5255. The Council's Web site, *www.mafmc.org* also has details on the meeting location, proposed agenda, webinar listen-in access, and briefing materials.

SUPPLEMENTARY INFORMATION: The following items are on the agenda, though agenda items may be addressed out of order (changes will be noted on the Council's Web site when possible).

Tuesday, October 4, 2016

Executive Committee

Review 2016 and proposed 2017 implementation plans.

River Herring and Shad (RH/S) Committee

Review updated decision document and develop Committee recommendations on whether to develop an amendment to add RH/S as Council-managed stocks.

Wednesday, October 5, 2016

Blueline Tilefish Framework—Meeting 1

Review background materials and approve range of alternatives.

Law Enforcement Reports

Reports will be received from the NOAA Office of Law Enforcement and the U.S. Coast Guard.

Spiny Dogfish Specifications

Review previously set 2017 specifications and consider any modifications if necessary.

New Jersey Special Management Zone (SMZ) Consideration

Review Monitoring Team Report for SMZ designation of 13 NJ artificial reefs.

River Herring and Shad Stocks in the Fishery

Review Committee recommendations and decide whether to develop an amendment to add RH/S as Council-managed stocks.

Council Communication and Outreach Plan

Review and discuss draft Communication and Outreach Plan

Thursday, October 6, 2016

Draft Environmental Assessment for Amendment 10 the Highly Migratory Species (HMS) FMP

Presentation of Amendment 10 HMS FMP by Jennifer Cudney of HMS, NMFS Southeast Fisheries Science Center (SEFSC) for Council review and comment.

Business Session

Organization Reports; Liaison Reports; Executive Director's Report; Science Report; Committee Reports; and Continuing and New Business.

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during these meetings. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: September 13, 2016.

Jeffrey N. Lonergan,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–22332 Filed 9–15–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE873

Western Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Western Pacific Fishery Management Council (Council) will hold its 124th Scientific and Statistical Committee (SSC) meeting, Fishing Industry Advisory Committee and its 168th Council meeting to take actions on fishery management issues in the Western Pacific Region.

DATES: The meetings will be held between October 4 and October 14. For specific dates, times and agendas, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: The 124th SSC will be held at the Council office, 1164 Bishop Street, Suite 1400, Honolulu, HI 96813, telephone: (808) 522–8220. The Fishing Industry Advisory Committee meeting will be held via teleconference, 1(888)482–3560; pass code 522–8220. The Council's Pelagic and International Standing Committee and Executive and Budget Standing Committee will also be held at the Council Office, 1164 Bishop Street, Suite 1400, Honolulu, HI, telephone: (808) 522–8220. The 168th Council meeting will be held at the Laniakea YWCA, Fuller Hall, 1040 Richards St., Honolulu, HI, telephone: (808) 538–7061. A Fishers Forum will be held at the Ala Moana Hotel, Garden Lanai room, 410 Atkinson Dr., Honolulu, HI 96814, telephone: (808) 955–4811.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director, phone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: The 124th SSC meeting will be held between 8:30 a.m. and 5 p.m. on October 4–6, 2016. The Fishing Industry Advisory Committee will be held between 4:00 p.m. and 6 p.m. (Hawaii Standard Time) on October 4, 2016. The Pelagic and International Standing Committee will be held between 9 a.m. and 12 noon on October 11, 2016. The Executive and Budget Standing Committee will be held on October 11, 2016 from 3 p.m. to 5 p.m. The first day of the 168th Council meeting will be on October 12, 2016, held from 8:30 a.m. to 11 a.m. The second and third days of the 168th Council meeting will be October 13–14, 2016, held from 8:30 a.m. to 5 p.m. On October 12, 2016, the Council will host a Fishers Forum between 6 p.m. and 9 p.m. at the Ala Moana Hotel, Garden Lanai Room. In addition to the agenda items listed here, the Council and its advisory bodies will hear recommendations from Council advisors. An opportunity to submit public comment will be provided throughout the agendas. The order in which agenda items are addressed may change and will be announced in advance at the Council meeting. The meetings will run as late as necessary to complete scheduled business. Background documents will be available from, and written comments should be sent to, Kitty M. Simonds, Executive Director; Western Pacific Fishery Management Council, 1164 Bishop Street, Suite 1400, Honolulu, HI 96813, phone: (808) 522–8220 or fax: (808) 522–8226.

Agenda for 124th SSC Meeting

Tuesday, October 4, 2016, 8:30 a.m. to 5 p.m.

1. Introductions
2. Approval of Draft Agenda and Assignment of Rapporteurs
3. Status of the 123rd SSC Meeting Recommendations
4. Report from the Pacific Islands Fisheries Science Center Director
5. Insular Fisheries
   A. Updates on the Hawaii Marine Recreational Fisheries Survey (HMRFS) data collection improvement project
   B. Updates on the State of Hawaii research and monitoring efforts
   C. Updates on The Nature Conservancy research and monitoring efforts
   D. Analysis of Hawaii Management Unit Species (MUS) catch for possible ecosystem component classification
   E. Productivity-Susceptibility Analysis and data-poor assessments

F. Biomass and spatial distribution of *Selar crumenopthalmus* from aerial surveys in Oahu
G. Public Comment
H. SSC Discussion and Recommendations
Plenary Speaker: Reflections on the Impact of Large Ocean Marine Protected Areas, Ray Hilborn
6. Program Planning
A. Expansion of NWHI Monument
1. Update
2. Economic impact of lost exclusive economic zone fishing grounds
B. Development of an integrated assessment model for data poor stocks
C. Marine Recreational Information Program (MRIP) Strategic Planning
D. Council Coral Reef Conservation Program FY 17–19 project proposals
E. Report on International Union for the Conservation of Nature (IUCN) World Conservation Congress
F. Public Comment
G. SSC Discussion and Recommendations

Wednesday, October 5, 2016, 8:30 a.m.–5 p.m.

7. Pelagic Fisheries
A. Report on the Pelagic Stock Assessment and Fishery Evaluation (SAFE) report development
B. Hawaii & American Samoa Longline Fisheries Reports
C. Report on American Samoa Large Vessel Prohibited Area (LVPA) and fisheries statistics
D. Western and Central Pacific Ocean (WCPO) Spatial Longline Bigeye Analysis
E. Report on WCPO and Eastern Pacific Ocean (EPO) Bigeye Tuna Limits
F. Factors resulting in recent increased Hawaii longline fishery bigeye CPUE
G. 2017 United States (U.S.) Participating Territory Bigeye Tuna Limits (Action Item)
H. Impact of Effort Limit Area for Purse Seine (ELAPS) on America Samoa Economy
I. International Fisheries
1. Western and Central Pacific Fisheries Commission (WCPFC) Science Committee
2. WCPFC Northern Committee
3. WCPFC Technical and Compliance Committee
4. Permanent Advisory Committee to U.S. Delegation to WCPFC
5. Continuation of 90th Inter-American Tropical Tuna Commission (IATTC) Plenary
J. Meta-regression analyses for shark catch rates
K. The Nature Conservancy Indo-Pacific Tuna Program
L. Public Comment
M. SSC Discussion and Recommendations
8. Protected Species
A. Hawaii Longline False Killer Whale Project Updates
1. Depredation mitigation device project
2. Acoustic monitoring of false killer whale depredation
B. Reconsultation of the Hawaii Deep-set longline fishery
C. Rare Events Bycatch Workshop Update
D. Updates on Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA) Actions
1. Humpback Whale Listing Final Rule
2. False Killer Whale Take Reduction Team
3. Insular False Killer Whale Recovery Planning
4. Other Actions
E. Public Comment
F. SSC Discussion and Recommendations

Thursday, October 6, 2016, 8:30 a.m. to 5 p.m.

9. Other Business
A. 125th SSC Meeting
10. Summary of SSC Recommendations to the Council

Agenda for the Fishing Industry Advisory Committee

Friday, October 7, 2016, 4 p.m. to 6 p.m.

1. Introduction and Welcome
2. Approval of Agenda
3. 2017 U.S. Participating Territory Bigeye Tuna Limit
4. Impacts of Effort Limit Area for Purse Seine (ELAPS)
5. Report on American Samoa Large Vessel Prohibited Area (LVPA) and fisheries statistics
6. Report on the Permanent Advisory Committee to U.S. Delegation to Western and Central Pacific Fisheries Commission
7. Seafood Traceability and Illegal, Unregulated and Unreported Fisheries
8. Public Comment
9. Discussion and Recommendations

Agenda for the Pelagic and International Standing Committee

Tuesday, October 11, 2016, 9 a.m. to 12 Noon

1. Addressing the Associated Press (AP) article on foreign crew in the Hawaii longline fleet
2. WCPO Spatial Longline Bigeye Analysis
3. Report on WCPO and EPO Bigeye Tuna Limits
4. 2017 U.S. Participating Territory Bigeye Tuna Limits (Action Item)
5. American Samoa LVPA exemption and recent fisheries statistics
6. International Fisheries Meetings
A. WCPFC Science Committee
B. WCPFC Northern Committee
C. WCPFC Technical and Compliance Committee
D. Permanent Advisory Committee to U.S. Delegation to WCPFC
E. Continuation of 90th IATTC Plenary
7. Advisory Group Report and Recommendations
A. Advisory Panel
B. Fishing Industry Advisory Committee
C. Scientific & Statistical Committee
8. Standing Committee Recommendations
9. Public Comment
10. Committee Discussion and Recommendations

Agenda for the Executive and Budget Standing Committee

Tuesday, October 11, 2016, 3 p.m. to 5 p.m.

1. Administrative Report
2. Financial Report
3. Expansion of NWHI Monument (Action Item)
A. Recommendations on implementing fishing provisions of the Papahanaumokuakea Monument expansion proclamation
B. Economic impact of lost EEZ fishing grounds
4. Addressing the AP article on foreign crew in the Hawaii longline fleet
5. Sustainable Hawaii Initiative
6. Regional Operating Agreement Essential Fish Habitat (EFH) Appendix
7. Meetings and Workshops
8. Council Family Changes
9. Other Issues
10. Public Comment
11. Committee Discussion and Recommendations

Agenda for the 168th Council Meeting

Wednesday, October 12, 2016, 8:30 a.m. to 11 a.m.

1. Welcome and Introductions
2. Oath of Office
3. Approval of the 168th Agenda
4. Approval of the 166th & 167th Meeting Minutes
5. Executive Director's Report
6. Agency Reports
A. National Marine Fisheries Service
1. Pacific Islands Regional Office
2. Pacific Islands Fisheries Science Center
B. NOAA Office of General Counsel, Pacific Islands Section

C. U.S. State Department
D. U.S. Fish and Wildlife Service
E. Enforcement
1. U.S. Coast Guard
2. NOAA Office of Law Enforcement
3. NOAA Office of General Counsel, Enforcement Section
F. Other Items
G. Public Comment
H. Council Discussion and Action

6 p.m.–9 p.m., Fishers Forum, Ala Moana Hotel, Garden Lanai Room, Honolulu

Thursday, October 13, 2016, 8:30 a.m. to 5 p.m.

7. Pelagic & International Fisheries
A. Addressing the AP article on foreign crew in the Hawaii longline fleet
B. Report on the Pelagic SAFE report development
C. Hawaii & American Samoa Longline Fisheries Reports
D. WCPO Spatial Longline Bigeye Analysis
E. Report on WCPO and EPO Bigeye Tuna Limits
F. 2017 U.S. Participating Territory Bigeye Tuna Limits (Action Item)
G. Impacts of ELAPS on American Samoa economy
H. American Samoa LVPA exemption and recent fisheries statistics
I. Update on Hawaii longline Electronic Reporting/Video Monitoring
J. International Fisheries Meetings
1. WCPFC Science Committee
2. WCPFC Northern Committee
3. WCPFC Technical and Compliance Committee
4. Permanent Advisory Committee to U.S. Delegation to WCPFC
5. Continuation of IATTC 90th Plenary
K. Advisory Group Report and Recommendations
1. Advisory Panel
2. Fishing Industry Advisory Committee
3. Scientific & Statistical Committee
L. Standing Committee Recommendations
M. Public Hearing
N. Council Discussion and Action
8. Program Planning and Research
A. Expansion of NWHI Monument (Action Item)
1. Recommendations on implementing fishing provisions of the Papahanaumokuakea Monument expansion proclamation
2. Economic impact of lost exclusive economic zone fishing grounds
B. MRIP Strategic Planning Workshop update
C. Council Coral Reef Conservation Program FY 17–19 project proposals
D. Updates on Marine National Monuments
1. National Marine Fisheries Service
2. U.S. Fish and Wildlife Service
E. Report on IUCN World Conservation Congress
F. Status of Aquaculture Programmatic Environmental Impact Statement
G. Regional, National and International Outreach & Education
H. Advisory Group Report and Recommendations
1. Advisory Panel
2. Social Science Planning Committee
3. Scientific & Statistical Committee
I. Public Hearing
J. Council Discussion and Action
9. Protected Species
A. Hawaii Longline False Killer Whale Project Updates
1. Depredation mitigation device project
2. Acoustic monitoring of false killer whale depredation
B. Re-consultation of the Hawaii Deep-set longline fishery
C. Rare Events Bycatch Workshop Update
D. Status of Marine Mammal Scientific Review Group Membership
E. Updates on ESA and Marine Mammal Protection Act Actions
1. Humpback Whale Listing Final Rule
2. False Killer Whale Take Reduction Team
3. Insular False Killer Whale Recovery Planning
4. Other Actions
F. Advisory Group Report and Recommendations
1. Advisory Panel
2. Scientific & Statistical Committee
G. Public Comment
H. Council Discussion and Action

Friday, October 14, 2016, 8:30 a.m. to 5 p.m.

10. Hawaii Archipelago & PRIA
A. Moku Pepa
B. Legislative Report
C. Enforcement Issues
D. Community Issues
1. Promise to Paeaina
2. Status of the Ohai Community Development Program (CDP) application
E. Report on IUCN and the Sustainable Hawaii Initiative
F. Analysis of Hawaii MUS catch for possible ecosystem component classification
G. Report on the Main Hawaiian Islands Deep-7 Bottomfish workshops
H. Updates on the HMRFS data collection improvement project
I. Update on State of Hawaii Research and Monitoring
J. Biomass and spatial distribution of *Selar crumenopthalmus* from aerial surveys in Oahu
K. Education and Outreach Initiatives
L. Advisory Group Report and Recommendations
1. Advisory Panel
2. Scientific & Statistical Committee
M. Public Comment
N. Council Discussion and Action
11. American Samoa Archipelago
A. Motu Lipoti
B. Fono Report
C. Enforcement Issues
D. Community Activities and Issues
1. Report on Pacific Island Regional Planning Body initiatives
E. Education and Outreach
F. Advisory Group Reports and Recommendations
1. Advisory Panel
2. Scientific & Statistical Committee
G. Public Comment
H. Council Discussion and Action
12. Mariana Archipelago
A. Guam
1. Isla Informe
2. Legislative Report
3. Enforcement Issues
4. Community Activities and Issues
a. Report on Yigo Community Planning
b. Report on sea cucumber regulations
c. Status of the Guam Fisheries Council
d. Military Expansion Issues
e. Report on Guam Coral Reef Fisheries Mapping
5. Education and Outreach Initiatives
B. Commonwealth of Northern Mariana Islands
1. Arongol Falú
2. Legislative Report
3. Enforcement Issues
4. Community Activities and Issues
a. Report on Northern Islands Community Planning
b. Military Expansion Issues
5. Education and Outreach Initiatives
C. Marianas Trench Marine National Monument Mapping Application
D. Advisory Group Reports and Recommendations
1. Advisory Panel
2. Scientific & Statistical Committee
E. Public Comment
F. Council Discussion and Action
13. Administrative Matters
A. Council Member and Staff Annual Training on Standards of Conduct
B. Financial Reports
C. Administrative Reports
D. Update on information inquiries and responses
E. Regional Operating Agreement—Essential Fish Habitat Appendix

F. Council Family Changes
G. Meetings and Workshops
H. Other Business
I. Standing Committee Recommendations
J. Public Comment
K. Council Discussion and Action
14. Election of Officers
15. Other Business

Non-emergency issues not contained in this agenda may come before the Council for discussion and formal Council action during its 168th meeting. However, Council action on regulatory issues will be restricted to those issues specifically listed in this document and any regulatory issue arising after publication of this document that requires emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 13, 2016.

Jeffrey N. Lonergan,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–22331 Filed 9–15–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE886

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Groundfish Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Monday, October 3, 2016 at 9:30 a.m.

ADDRESSES: The meeting will be held at the Hilton Garden Inn Boston Logan Airport, 100 Boardman Street, Boston, MA 02128; phone: (617) 567–6789; fax: (617) 561–0798.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Committee will discuss Framework Adjustment 56 specifications, management measures, and draft alternatives and make recommendations to the Council. They will receive a progress report from the Plan Development Team on the white paper on monitoring strategies and develop recommendations to the Council. The Committee will also discuss possible groundfish priorities for 2017 and develop final recommendations to the Council. Other business will be discussed as necessary.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 13, 2016.

Jeffrey N. Lonergan,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–22335 Filed 9–15–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0649–XE885

Gulf of Mexico Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council will hold a meeting of its Reef Fish Advisory Panel (AP).

DATES: The meeting will convene on Tuesday, October 4, 2016, from 8:30 a.m. to 5 p.m. and Wednesday, October 5, 2016, from 8:30 a.m. to 4 p.m. EDT.

ADDRESSES: The meeting will take place at the Gulf of Mexico Fishery Management Council Office, 2203 N. Lois Avenue, Suite 1100, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Dr. Carrie Simmons, Deputy Director, Gulf of Mexico Fishery Management Council; *carrie.simmons@gulfcouncil.org;* telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION:

Agenda

The Chairman will start the meeting with introductions and adoption of agenda. The AP will review and approve the minutes of two previous meetings held September 16–17, 2015 and April 1, 2016, respectively. The AP will review and discuss the Draft Proposed Fishing Regulations for Flower Garden Banks National Marine Sanctuary Expansion and a Draft Scoping Document to Evaluate Recommended Coral Areas as Habitat Areas of Particular Concern (HAPCs). The AP will review and comment on Reef Fish Amendment 36A Commercial IFQ Modifications; Reef Fish Amendment 46 Gray Triggerfish Rebuilding Plan; a Draft Framework Action to Modify Mutton Snapper Annual Catch Limits and Management Measures including an Action to Modify the Commercial Gag Minimum Size Limit. The AP will also hear a presentation on the results of the Vermilion Snapper Stock Assessment and Scientific and Statistical Committee Recommendations. The AP will review and comment on Draft Options to Modify Vermilion Snapper ACLs and Maximum Sustainable Yield Proxies. The AP will also receive a presentation on the Goliath Grouper Assessment and

Scientific and Statistic Committee Recommendations. The AP will review and provide recommendations on Modifications to Charter Vessel and Headboat Reporting Requirements and have a discussion on the Carryover of any Underharvested Red Snapper Annual Catch Limit to the Following Season. Under Other Business, the AP will discuss and potentially make recommendations on a Recreational and Commercial Allocation Exchange to the Council.

—Meeting Adjourns—

The Agenda is subject to change, and the latest version along with other meeting materials will be posted on the Council's file server. To access the file server, the URL is *https://public.gulfcouncil.org:5001/webman/index.cgi,* or go to the Council's Web site and click on the FTP link in the lower left of the Council Web site (*http://www.gulfcouncil.org*). The username and password are both "gulfguest". Click on the "Library Folder", then scroll down to "Reef Fish AP 10–2016".

The meeting will be webcast over the internet. A link to the webcast will be available on the Council's Web site, *http://www.gulfcouncil.org.*

Although other non-emergency issues not on the agenda may come before the AP for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during this meeting. Actions of the AP will be restricted to those issues specifically identified in the agenda and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Gulf Council Office (see **ADDRESSES**), at least 5 working days prior to the meeting.

Dated: September 13, 2016.

Jeffrey N. Lonergan,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–22333 Filed 9–15–16; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed deletions from the Procurement List.

SUMMARY: The Committee is proposing to delete products and services from the Procurement List that was previously furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

Comments Must Be Received on or Before: 10/16/2016.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following products and services are proposed for deletion from the Procurement List:

Products

NSN(s)—Product Name(s): 7510–00–NIB–0432—Business Card Case, Fold-Up, Rosewood

Mandatory Source(s) of Supply: Tarrant County Association for the Blind, Fort Worth, TX

Contracting Activity: General Services Administration, New York, NY

NSN(s)—Product Name(s):

MR 10468—Set, Saver, Salad
MR 10674—Funnel, Collapsible
MR 10635—Serving Platter, Heavy Duty, Raised Surface, Fall Themed, White
MR 10627—Garden Seed Packets, Assorted, 4PK
MR 10623—Container, Frozen Waffle, Expandable
MR 10618—Stickers, Easter Themed, Assorted, 200ct
MR 10626—Poster Book, Coloring, Assorted, 36 x 42
MR 10609—Bowl, Insulated Thermal, Toddler, 8oz
MR 380—Set, Baking Cups and Picks, Holiday, 24PC
MR 382—Duct Tape, Holiday Themed, Assorted Colors

Mandatory Source(s) of Supply: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC

Contracting Activity: Defense Commissary Agency

NSN(s)—Product Name(s):

MR 1120—Bag, Storage, Vacuum Sealed, 6PG
MR 365—Serving Set, Stand and Bowl, Halloween Themed, 16oz
MR 371—Serving Set, Stand and Bowl, Holiday Themed, 16oz
MR 1146—Serving Set, Stand and Bowl, 16oz
MR 349—Containers, Storage, 6PG
MR 370—Serving Bowl, Holiday, Plastic 7Qt
MR 373—Chip and Dip Bowl, Holiday, Plastic
MR 301—Silicone Spatula
MR 355—Set, Serving Set, Party Travelling
MR 1183—Set, Mixing Bowl, Melamine, 4PC
MR 1159—Set, Bakeware, Cake Pop
MR 383—Server, Beverage, w Spout, 1.25G

Mandatory Source(s) of Supply: Industries for the Blind, Inc., West Allis, WI

Contracting Activity: Defense Commissary Agency

NSN(s)—Product Name(s):

6515–00–NIB–0770—Gloves, Surgical, Powder-free, OR Classic, White, Size 8″
6515–00–NIB–0771—Gloves, Surgical, Powder-free, OR Classic, White, Size 8.5″
6515–00–NIB–0772—Gloves, Surgical, Powder-free, OR Classic, White, Size 9″
6515–00–NIB–0773—Gloves, Surgical, Powder free, Sensicare Ortho, White, Size 5.5″
6515–00–NIB–0765—Gloves, Surgical, Powder-free, OR Classic, White, Size 5.5″
6515–00–NIB–0766—Gloves, Surgical, Powder-free, OR Classic, White, Size 6″
6515–00–NIB–0767—Gloves, Surgical, Powder-free, OR Classic, White, Size 6.5″
6515–00–NIB–0768—Gloves, Surgical, Powder-free, OR Classic, White, Size 7″
6515–00–NIB–0769—Gloves, Surgical, Powder-free, OR Classic, White, Size 7.5″
6515–00–NIB–0680—Gloves, Surgical, Powder-free, Derma Prene, Isotouch Hydrasoft, Green, Size 8.5″
6515–00–NIB–0681—Gloves, Surgical, Powder-free, Derma Prene, Isotouch Hydrasoft, Green, Size 9″
6515–00–NIB–0674—Gloves, Surgical, Powder-free, Derma Prene, Isotouch Hydrasoft, Green, Size 5.5″
6515–00–NIB–0675—Gloves, Surgical, Powder-free, Derma Prene, Isotouch Hydrasoft, Green, Size 6″
6515–00–NIB–0676—Gloves, Surgical, Powder-free, Derma Prene, Isotouch Hydrasoft, Green, Size 6.5″
6515–00–NIB–0677—Gloves, Surgical, Powder-free, Derma Prene, Isotouch Hydrasoft, Green, Size 7″
6515–00–NIB–0678—Gloves, Surgical, Powder-free, Derma Prene, Isotouch Hydrasoft, Green, Size 7.5″
6515–00–NIB–0679—Gloves, Surgical, Powder-free, Derma Prene, Isotouch Hydrasoft, Green, Size 8″

Mandatory Source(s) of Supply: Bosma Industries for the Blind, Inc., Indianapolis, IN

Contracting Activity: Strategic Acquisition Center, Fredericksburg, VA

NSN(s)—Product Name(s): 6515–00–NIB–

8015—Gloves, Exam, Nitrile, Latex-Free, Powder-Free, W/Inner Aloe coating, 5.5 mil (palm), Green, x-Small
Mandatory Source(s) of Supply: Bosma Industries for the Blind, Inc., Indianapolis, IN
Contracting Activity: Department of Veterans Affairs

NSN(s)—Product Name(s): 7220–00–NIB–0143—Safety-Walk, Tapes & Treads—310 Black Medium Resilient
Mandatory Source(s) of Supply: Louisiana Association for the Blind, Shreveport, LA
Contracting Activity: General Services Administration, New York, NY

NSN(s)—Product Name(s): 8030–01–596–4258—Lubricant, 5-in-1 Penetrating Multipurpose oil, Biobased, Aerosol, 11 oz. net
Mandatory Source(s) of Supply: The Lighthouse for the Blind, St. Louis, MO
Contracting Activity: Defense Logistics Agency Troop Support

NSN(s)—Product Name(s):
6515–00–NIB–0531—Glove Powder Free, aloetouch micro
6515–00–NIB–0532—Glove Powder Free, aloetouch micro
6515–00–NIB–0533—Glove Powder Free, aloetouch micro
6515–00–NIB–0534—Glove Powder Free, aloetouch micro
6515–00–NIB–0535—Glove Powder Free, aloetouch micro
6515–00–NIB–0536—Glove Powder Free, aloetouch micro
6515–00–NIB–0537—Glove Powder Free, aloetouch micro
6515–00–NIB–0538—Glove Powder Free, aloetouch micro
6515–00–NIB–0481—Glove Powdered, Perry Orthopaedic
6515–00–NIB–0482—Glove Powdered, Perry Orthopaedic
6515–00–NIB–0483—Glove Powdered, Perry Orthopaedic
6515–00–NIB–0477—Glove Powdered, Perry Orthopaedic
6515–00–NIB–0478—Glove Powdered, Perry Orthopaedic
6515–00–NIB–0479—Glove Powdered, Perry Orthopaedic
6515–00–NIB–0461—Glove Powdered, Original Perry Style 42
6515–00–NIB–0462—Glove Powdered, Original Perry Style 42
6515–00–NIB–0463—Glove Powdered, Original Perry Style 42
6515–00–NIB–0464—Glove Powdered, Original Perry Style 42
6515–00–NIB–0465—Glove Powdered, Original Perry Style 42
6515–00–NIB–0466—Glove Powdered, Original Perry Style 42
6515–00–NIB–0467—Glove Powdered, Original Perry Style 42
6515–00–NIB–0468—Glove Powdered, Original Perry Style 42
6515–00–NIB–0208—Glove, Surgeon, Biogel Neotech, Size 5.5
6515–00–NIB–0209—Glove, Surgeon, Biogel Neotech, Size 6.0
6515–00–NIB–0210—Glove, Surgeon, Biogel Neotech, Size 6.5
6515–00–NIB–0211—Glove, Surgeon, Biogel Neotech, Size 7.0
6515–00–NIB–0212—Glove, Surgeon, Biogel Neotech, Size 7.5
6515–00–NIB–0213—Glove, Surgeon, Biogel Neotech, Size 8.0
6515–00–NIB–0214—Glove, Surgeon, Biogel Neotech, Size 8.5
6515–00–NIB–0215—Glove, Surgeon, Biogel Neotech, Size 9.0
6515–00–NIB–0192—Glove, Surgeon, Biogel Orthopaedic, Size 5.5
Mandatory Source(s) of Supply: Bosma Industries for the Blind, Inc., Indianapolis, IN
Contracting Activity: Department of Veterans Affairs

Services

Service Type: Temp. Admin/General Support Service
Mandatory for: National Institute of Health, 31 Center Dr., Bethesda, MD
Mandatory Source(s) of Supply: Columbia Lighthouse for the Blind, Washington, DC
Contracting Activity: Dept of Health and Human Services

Service Type: Medical Transcription Service
Mandatory for:
Corpus Christi Naval Air Station: Naval Hospital, 10651 E Street, Bldg H–100, Corpus Christi, TX
U.S. Naval Hospital, 3600 Rivers Ave., North Charleston, SC
Mandatory Source(s) of Supply: Lighthouse for the Blind of Houston, Houston, TX
Contracting Activity: DOD/Department of the Navy

Service Type: Administrative/General Support Service
Mandatory for: GSA, Southwest Supply Center, 819 Taylor Street, Fort Worth, TX
Mandatory Source(s) of Supply:
Lighthouse for the Blind of Houston, Houston, TX
West Texas Lighthouse for the Blind, San Angelo, TX
South Texas Lighthouse for the Blind, Corpus Christi, TX
Contracting Activity: General Services Administration, FPDS Agency Coordinator

Barry S. Lineback,
Director, Business Operations.

[FR Doc. 2016–22324 Filed 9–15–16; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletions from the Procurement List.

SUMMARY: This action deletes products from the Procurement List previously furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Effective Date:* 10/16/2016.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Deletions

On 8/12/2016 (81 FR 53466), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.
2. The action may result in authorizing small entities to furnish the products to the Government.
3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products deleted from the Procurement List.

End of Certification

Accordingly, the following products are deleted from the Procurement List:

Products

NSN(s)—Product Name(s): 2540–01–071–2051—Cover, Cushion Assembly
Mandatory Source(s) of Supply: Pioneer Vocational/Industrial Services, Inc., Danville, KY
Contracting Activity: Defense Logistics Agency Land and Maritime

NSN(s)—Product Name(s):
7530–01–071–9792—Paper, Bond, Dual Purpose, Opaque Buff, 8.5″ x 11″
7530–01–148–1766—Paper, Xerographic, Dual Purpose, Buff, 8.5″ x 11″
Mandatory Source(s) of Supply: Louisiana Association for the Blind, Shreveport, LA
Contracting Activity: General Services Administration, New York, NY

NSN(s)—Product Name(s): 6540–01–131–7919—Case, Spectacles
Mandatory Source(s) of Supply: Dallas Lighthouse for the Blind, Inc., Dallas, TX
Contracting Activity: Defense Logistics Agency Troop Support

Barry S. Lineback,
Director, Business Operations.
[FR Doc. 2016–22325 Filed 9–15–16; 8:45 am]
BILLING CODE 6353–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Proposed Information Collection; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed.

Currently, CNCS is soliciting comments concerning the data elements and questions that will be collected on its Grantee Progress Report (GPR) for the following grant programs: AmeriCorps State and National operating grants, AmeriCorps State and National planning grants, School Turnaround AmeriCorps grants, Volunteer Generation Fund grants, Commission Investment Funds grants, and State Commission Support grants. All grantees of these programs are required to complete a full annual GPR and an abbreviated mid-year GPR six months prior to the annual GPR. Grantees also complete an abbreviated final GPR, which is identical to the mid-year GPR, at the end of their overall grant period. The GPR provides information for CNCS staff to monitor grantee progress and to respond to requests from Congress and other stakeholders.

Copies of the information collection request can be obtained by contacting the office listed in the *ADDRESSES* section of this notice.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by November 15, 2016.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) *By mail sent to:* Corporation for National and Community Service, AmeriCorps State and National, Attention Carla Ganiel, Senior Program and Project Specialist, Room 3221D, 250 E Street SW., Washington, DC 20024.

(2) By hand delivery or by courier to the CNCS mailroom at Room 4300 at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except Federal holidays.

(3) Electronically through *www.regulations.gov.*

Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Carla Ganiel, 202–606–6773, or by email at *cganiel@cns.gov.*

SUPPLEMENTARY INFORMATION: CNCS is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are expected to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submissions of responses).

Background

Currently, all grantees of the AmeriCorps State and National, School Turnaround AmeriCorps, the Volunteer Generation Fund, and Commission Support programs complete the annual GPR, mid-year GPR, and final GPR, which provide information for CNCS staff to monitor grantee progress and to respond to requests from Congress and other stakeholders. The information is collected electronically through the eGrants system.

Current Action

CNCS seeks to renew the current information collection for programs which currently complete the GPR, and expand the use of the GPR to include two additional grant programs, the Commission Investment Funds and AmeriCorps State and National Planning Grants. CNCS has revised its GPRs to ensure consistency and reduce duplication across these grant programs. The information collection will otherwise be used in the same manner as the existing GPR. CNCS also seeks to continue using the current application until the revised GPR information collection is approved by OMB. The current GPR information collections are due to expire as follows: AmeriCorps State and National expires January 31, 2017; School Turnaround AmeriCorps expires March 31, 2017; Volunteer Generation Fund expires November 30, 2017; Commission Support Grant expires December 31, 2017.

Type of Review: New.

Agency: Corporation for National and Community Service.

Title: Grantee Progress Report.

OMB Number: TBD.

Agency Number: None.

Affected Public: Grantees who receive grants in the following programs: AmeriCorps State and National, School Turnaround AmeriCorps, Volunteer Generation Fund, Commission Support, Commission Investment Funds, AmeriCorps State and National Planning Grants.

Total Respondents: 672 responses.

Frequency: Semi-annual.

Average Time per Response: 8 hours.

Estimated Total Burden Hours: 5,376.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: September 12, 2016.

Bill Basl,
Director, AmeriCorps State and National.
[FR Doc. 2016–22243 Filed 9–15–16; 8:45 am]
BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Department of the Army, U. S. Army Corps of Engineers

Withdrawal of Notice of Intent To Prepare a Supplemental Environmental Impact Statement for the Raritan Bay and Sandy Hook Bay, New Jersey Feasibility Report for Hurricane and Storm Damage Reduction Union Beach, New Jersey Final Feasibility Report

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of Intent; Withdrawal.

SUMMARY: The U.S. Army Corps of Engineers, New York District (NY District), is withdrawing its intent to prepare a Draft Supplemental Environmental Impact Statement (SEIS) for the Study. The Notice of Intent to prepare the SEIS was published in the Friday, January 24, 2014, issue of the **Federal Register** (79 FR 4155).

ADDRESSES: U.S. Army Corps of Engineers, New York District, Planning Division, Environmental Analysis Branch, 26 Federal Plaza, Room 2151, New York, NY 10278–0090.

FOR FURTHER INFORMATION CONTACT: Matthew Voisine, Project Biologist, at *matthew.voisine@usace.army.mil* or 917.790.8718.

SUPPLEMENTARY INFORMATION: The U.S. Army Corps of Engineers, NY District published a notice of intent to prepare a Supplemental Environmental Impact Statement in the January 24, 2014 issue of the **Federal Register** (FR Doc. 2014–01443). Since that time, resource agency involvement through meetings, changes in plan formulation, and re-evaluation of the project have reduced the magnitude and extent of proposed flood risk management measures and associated environmental impacts to the point that an SEIS is no longer necessary. A Supplemental Environmental Assessment will be prepared and circulated for review by agencies and the public. The NY District invites participation and consultation of agencies and individuals that have special expertise, legal jurisdiction, or interest in the preparation of the draft environmental assessment. Comments received, including the names and addresses of those who comment, will be considered part of the public record for this proposal. As a result of the process, if it is determined that the project may have significant impacts, the EIS process will be reinitiated and a NOI published.

Peter Weppler,

Chief, Environmental Analysis Branch.

[FR Doc. 2016–22336 Filed 9–15–16; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Record of Decision for the Remaining Balanced Vision Plan and Interior Drainage Plan Features Feasibility Report and Environmental Impact Statement, Dallas County, TX

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice.

SUMMARY: The U.S. Army Corps of Engineers (USACE), Fort Worth District, is issuing this notice to advise Federal, state, and local governmental agencies and the public that USACE has signed a Record of Decision (ROD) for the Remaining Balanced Vision Plan (BVP) and Interior Drainage Plan (IDP) Features *Feasibility Report* and *Final Environmental Impact Statement,* in Dallas County, TX. This ROD was rendered to declare that a USACE action, a Section 408 Permission for the City of Dallas to alter the Dallas Floodway, is in the public interest.

DATES: The USACE Fort Worth District Commander, Colonel Calvin C. Hudson II, signed the ROD and Section 408 Permission on July 28, 2016.

ADDRESSES: U.S. Army Corps of Engineers, Regional Planning and Environmental Center, CESWF–PEC–CC (Attn: Mr. Jason Story), P.O. Box 17300, Room 3A12, Fort Worth, TX 76102–0300.

FOR FURTHER INFORMATION CONTACT: Jason Story, Environmental Resources Specialist, Regional Planning and Environmental Center. Email address: *jason.e.story@usace.army.mil.*

SUPPLEMENTARY INFORMATION: The City of Dallas has requested permission to construct the Dallas Floodway Project remaining BVP and IDP features in Dallas County, TX. These remaining BVP and IDP features will constitute an alteration of the existing Dallas Floodway, a USACE federally authorized civil works project that requires Title 33 United States Code, Section 408 (Section 408) compliance. The proposed alterations within the Dallas Floodway consist of ecosystem restoration, recreation, and interior drainage improvements. These alterations were analyzed in the *Final Feasibility Report* and disclosed in the *Final Environmental Impact Statement* dated December 2014, for the Dallas Floodway Project. This ROD addresses the USACE Section 408 Permission.

Douglas C. Sims,

Chief, Environmental Compliance Branch, Regional Planning and Environmental Center.

[FR Doc. 2016–22321 Filed 9–15–16; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF EDUCATION

[Catalog of Federal Domestic Assistance (CFDA) Number: 84.215N]

Reopening and Extension of the Application Deadline Date for the Fiscal Year 2016 Competition; Promise Neighborhoods Program

AGENCY: Office of Innovation and Improvement, Department of Education.

ACTION: Notice.

SUMMARY: The Assistant Deputy Secretary for Innovation and Improvement reopens the competition and extends the deadline date for transmittal of applications for new awards for fiscal year (FY) 2016 under the Promise Neighborhoods program. The Assistant Deputy Secretary takes this action to allow more time for the preparation and submission of applications by prospective eligible applicants. We are reopening the competition and extending the application deadline date, from September 6, 2016 to September 16, 2016, for all applicants, due to the impact of severe weather-related issues across the country.

DATES:

Deadline for Transmittal of Applications: September 16, 2016.

Deadline for Intergovernmental Review: November 15, 2016.

SUPPLEMENTARY INFORMATION: On July 8, 2016, we published in the **Federal Register** (81 FR 44741) a notice inviting applications (NIA) for new awards for FY 2016 for the Promise Neighborhoods competition. On August 31, 2016, we published in the **Federal Register** a notice extending the deadline for transmittal of applications to allow certain eligible applicants affected by the flooding in Louisiana additional time to prepare and transmit their applications. At this time, we are reopening the Promise Neighborhoods competition and extending the deadline for transmittal of applications to allow all eligible applicants more time to prepare and submit their applications due to severe weather-related issues across the country.

Eligibility: The reopening of the competition and extension of the application deadline date in this notice applies to all applicants under the Promise Neighborhoods program.

In accordance with the application notice, an eligible organization for the Promise Neighborhoods program—

(1) Is representative of the geographic area proposed to be served;

(2) Is one of the following:

(a) A nonprofit organization that meets the definition of a nonprofit under 34 CFR 77.1(c), which may include a faith-based nonprofit organization.

(b) An institution of higher education as defined by section 101(a) of the Higher Education Act of 1965, as amended.

(c) An Indian tribe as defined in the NIA;

(3) Currently provides at least one of the solutions from the applicant's proposed continuum of solutions in the geographic area proposed to be served; and

(4) Operates or proposes to work with and involve in carrying out its proposed project, in coordination with the school's LEA, at least one public elementary or secondary school located within the identified geographic area that the grant will serve.

Note: Except for the deadline date, all information in the application notice for this competition remains the same.

Program Authority: Fund for the Improvement of Education, title V, part D, subpart 1, sections 5411 through 5413 of the Elementary and Secondary Education Act of 1965, as amended by the No Child Left Behind Act of 2001 (20 U.S.C. 7243–7243b).

FOR FURTHER INFORMATION CONTACT: Adrienne Hawkins, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W256, Washington, DC 20202. Telephone: (202) 453–5638. Email address: *PromiseNeighborhoods@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact persons listed under **FOR FURTHER INFORMATION CONTACT** in this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: September 12, 2016.

Nadya Chinoy Dabby,

Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 2016–22242 Filed 9–15–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

National Advisory Council on Indian Education; Announcement of an Open Public Meeting

AGENCY: National Advisory Council on Indian Education (NACIE), Department of Education.

ACTION: Announcement of an open public meeting.

SUMMARY: This notice sets forth the schedule of an upcoming public meeting conducted by the National Advisory Council on Indian Education (NACIE). Notice of the meeting is required by Section 10(a)(2) of the Federal Advisory Committee Act and is intended to notify the public of its opportunity to attend.

DATES: The NACIE meeting will be held on September 28–29, 2016, 8:30 a.m.–4:00 p.m. each day, Eastern Daylight Saving Time. The meeting will be held at the Residence Inn by Marriott located at 333 E Street SW., Washington, DC 20024. Phone 202–484–8280.

FOR FURTHER INFORMATION CONTACT: Tina Hunter, Designated Federal Official, Office of Elementary and Secondary Education, U.S. Department of Education, 400 Maryland Avenue SW., Washington, DC 20202. Telephone: 202–205–8527. Fax: 202–205–0310.

SUPPLEMENTARY INFORMATION:

NACIE's Statutory Authority and Function: NACIE is authorized by Section 7471 of the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the Every Student Succeeds Act (ESSA). NACIE is governed by the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, which sets forth requirements for the formation and use of advisory committees. NACIE is established within the U.S. Department of Education (Department) to advise the Secretary of Education (Secretary) on the funding and administration (including the development of regulations and administrative policies and practices) of any program over which the Secretary has jurisdiction and that includes Indian children or adults as participants or that may benefit Indian children or adults, including any program established under Title VI, Part A of the ESEA. NACIE makes recommendations to the Secretary for filling the position of Director of Indian Education whenever a vacancy occurs. NACIE submits to the Congress, not later than June 30 of each year, a report on the activities of NACIE that includes recommendations NACIE considers appropriate for the improvement of Federal education programs that include Indian children or adults as participants or that may benefit Indian children or adults, and recommendations concerning the funding of any such program.

Meeting Agenda: The purpose of the meeting is to convene NACIE to conduct the following committee business: (1) Compile information to be included in the 2016 letter to the Secretary; (2) Receive an overview from Department staff regarding Department programs and their impact on Indian children and adults; and (3) Conduct discussions and begin work on the development of a report of accomplishments by NACIE.

Submission of written public comments: Due to the full agenda on both meeting days, there will not be a public comment period at the meeting. However, if you wish to submit written comments related to the NACIE, all written comments must be received by September 21, 2016 at: *oese@ed.gov.* Please include in the subject line "NACIE Written Comments''. The email must include the name(s), title, organization/affiliation, mailing address, email address, and telephone number, of the person(s) making the comment. Comments should be submitted as a Microsoft Word document or in a medium compatible with Microsoft Word (not a PDF file) that is attached to an electronic mail message (email) or provided in the body of an email message. Please do not send material directly to the NACIE members.

Access to Records of the Meeting: The Department will post the official report of the meeting on the Office of Elementary and Secondary Education (OESE) Web site at: *http://www2.ed.gov/about/offices/list/oese/index.html?src=oc* 21 days after the meeting. Pursuant to the FACA, the public may also inspect the materials at the Office of Indian Education, U.S. Department of Education, 400 Maryland Avenue SW., Washington, DC 20202, Monday-Friday, 8:30 a.m. to 5:00 p.m. Eastern Daylight Saving Time or by emailing *TribalConsultation@ed.gov* or by calling Terrie Nelson on (202) 401–0424 to schedule an appointment.

Reasonable Accommodations: The meeting is accessible to individuals with disabilities. If you will need an auxiliary aid or service to participate in the meeting (*e.g.,* interpreting service, assistive listening device, or materials in an alternate format), notify Brandon Dent on (202) 453–6450 no later than September 21, 2016. Although we will attempt to meet a request received after request due date, we may not be able to make available the requested auxiliary aid or service because of insufficient time to make arrangements.

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys*. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov*. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Ann Whalen,

Delegated the authority to perform the functions and duties of Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2016–22245 Filed 9–15–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0101]

Agency Information Collection Activities; Comment Request; Common Core of Data (CCD) School-Level Finance Survey (SLFS) 2016–2018

AGENCY: National Center for Education Statistics (NCES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before November 15, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0101. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E–347, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact NCES Information Collections at *NCES.Information.Collections@ed.gov.*

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Common Core of Data (CCD) School-Level Finance Survey (SLFS) 2016–2018.

OMB Control Number: 1850—NEW.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 306.

Total Estimated Number of Annual Burden Hours: 4,938.

Abstract: In response to a growing demand, the National Center for Education Statistics (NCES), within the U.S. Department of Education, has developed and conducted a pilot, in 2015 and 2016 (OMB #1850–0803), of a new collection of finance data at the school level. The School-Level Finance Survey (SLFS) centrally collects school-level finance data form state education agencies (SEAs), and is an extension of two existing collections conducted by NCES, in collaboration with the U.S. Census Bureau, the School District Finance Survey (F–33) and the state-level National Public Education Financial Survey (NPEFS). The Every Student Succeeds Act (ESSA) signed into law on December 10, 2015, requires SEAs and local agencies to produce report cards for the 2017–18 school year that include per-pupil actual personnel and nonpersonnel expenditures of Federal, State, and local funds, disaggregated by source of funds, for each local educational agency (LEA) and each school in the State for the preceding fiscal year. SLFS collects 30 expenditure items, 12 of which are "personnel" and 18 "nonpersonnel" expenditures. The SLFS data items and definitions are consistent with those in the NPEFS and F–33 surveys. The first year of the pilot SLFS data collection (for fiscal year FY 2014) commenced on May 7, 2015, with 12 SEAs participating, and the second year of data collection (for FY 2015) commenced on April 4, 2016, with 19 SEAs participating. This request is to annually collect national SLFS data in 2017 through 2019, covering FY 2016 through 2018, and corresponding to school years 2015/16 through 2017/18.

Dated: September 13, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–22302 Filed 9–15–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Energy Information Administration

Agency Information Collection Extension

AGENCY: U.S. Energy Information Administration (EIA), Department of Energy.

ACTION: Agency information collection activities: Information collection extension with change, comment request.

SUMMARY: The EIA, pursuant to the Paperwork Reduction Act of 1995, intends to submit an information collection request for the Coal Markets Reporting System, OMB Control Number 1905–0167, with the Office of Management and Budget (OMB). EIA is soliciting comments on the proposed revisions and requests a three-year extension to Forms:

EIA–3 "Quarterly Survey of Non-Electric Sector Coal Data"
EIA–7A "Annual Survey of Coal Production and Preparation"
EIA–8A "Annual Survey of Coal Stocks and Coal Exports"

No changes are proposed for Forms:

EIA–6 "Emergency Coal Supply Survey (Standby)"
EIA–20 "Emergency Weekly Coal Monitoring Survey for Coal Burning Power Producers (Standby)"

The EIA proposes to make moderate changes to questions, response options, and instructions to Forms EIA–3, EIA–7A, and EIA–8A and requests an extension to Forms EIA–6 and EIA–20 with no substantive changes. EIA is proposing to require submission of Form EIA–3 and EIA–8A through the U.S. Energy Information Administration Data xChange Portal and will eliminate unsecured reporting modes. The Data xChange Portal:

- Serves as a single point of entry for authorized users to respond to EIA surveys, access EIA data, and build customized reports.
- Provides expanded communication methods to include phone and email contact information of centralized data collection team
- Uses security protocols to protect the information against unauthorized access during transmission.
- Requires data submission through an online web form, eliminating unsecured reporting methods.

DATES: Comments must be filed by November 15, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, please advise the EIA–7A Survey Manager at EIA of your intention to make a submission as soon as possible. The Survey Manager may be contacted by email at *JenAlyse.Arena@eia.gov* or by telephone at 202–586–4866.

ADDRESSES: Written comments should be sent to: Attn: JenAlyse Arena, EIA–7A Survey Manager, U.S. Energy Information Administration, EI–24, 1000 Independence Avenue SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of any forms and instructions should be directed to Ms. JenAlyse Arena at the contact information listed above. The proposed forms and instructions are available on the Internet at: *http://www.eia.gov/survey/changes/coal/2016/*.

SUPPLEMENTARY INFORMATION: This information collection request contains:

(1) OMB No. 1905–0167;

(2) Information Collection Request Title: Coal Markets Reporting System. The survey forms:

EIA–3 "Quarterly Survey of Non-Electric Sector Coal Data"
EIA–7A "Annual Survey of Coal Production and Preparation"
EIA–8A "Annual Survey of Coal Stocks and Coal Exports"
EIA–6 "Emergency Coal Supply Survey (Standby)"
EIA–20 "Emergency Weekly Coal Monitoring Survey for Coal Burning Power Producers (Standby)"

(3) Type of Request: Three-year extension with changes;

(4) Purpose: The Federal Energy Administration Act of 1974 (15 U.S.C. 761 *et seq.*) and the DOE Organization Act (42 U.S.C. 7101 *et seq.*) require the EIA to carry out a centralized, comprehensive, and unified energy information program. This program collects, evaluates, assembles, analyzes, and disseminates information on energy resource reserves, production, demand, technology, and related economic and statistical information. This information is used to assess the adequacy of energy resources to meet near and longer term domestic demands and to promote sound policymaking, efficient markets, and public understanding of energy and its interaction with the economy and the environment.

The EIA, as part of its effort to comply with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*), provides the general public and other Federal agencies with opportunities to comment on collections of energy information conducted by, or in conjunction with, the EIA. Also, the EIA will later seek approval for this collection from the Office of Management and Budget (OMB) under Section 3507(a) of the Paperwork Reduction Act of 1995.

EIA surveys are conducted to collect coal market data. The data elements include production, consumption, receipts, stocks, sales, and prices. Information pertaining to the quality of the coal is also collected. Aggregates of this collection are used to support public policy analyses of the coal industry, economic modeling, forecasting, coal supply and demand studies, and in guiding research and development programs. EIA publications, including the *Monthly Energy Review, Quarterly Coal Report, Quarterly Coal Distribution Report, Annual Coal Report,* and *Annual Coal Distribution Report,* each contain data collected through the coal production and consumption surveys listed above.

In addition, the EIA uses the data in short-term and long-term models such as the Short-Term Integrated Forecasting System (STIFS) and the National Energy Modeling System (NEMS) Coal Market Module. The forecast data also appear in the *Short-Term Energy Outlook* and the *Annual Energy Outlook* publications.

Please refer to the proposed forms and instructions for more information about the purpose, who must report, when to report, where to submit, elements to be reported, detailed instructions, provisions for confidentiality, and uses of the information.

(4a) *Proposed Changes:* EIA will be requesting a three-year extension of approval for all its coal surveys with the following changes:

Form EIA–3: Quarterly Survey of Non-Electric Sector Coal Data

- Change the title of the survey to "Quarterly Survey of Industrial, Commercial, & Institutional Coal Users"
- In Part 2, Question 6, revise reporting for co-fired sites to allow reporting of more than one additional fuel source.
- In Part 3, Question 2, remove Adjustments to total cost of coal received during the reporting cycle.
- In Part 5, Questions 2–3, revise coking plant disposition categories and

include distinction between domestic and export sales of coke and breeze to gather more accurate data on each type of sale.

- In Part 8, Question 2, revise coal refining plant disposition categories to allow for accurate accounting of refined coal.

EIA proposes adding the following questions to Form EIA–3:

- In Part 2, Question 2, add the question: *"Does this site operate a coke oven"?* This question will be used to identify active U.S. coking plants within manufacturing sites.
- In Part 3, Question 3A, add the question *"Please provide the contact information for your broker."* Contact information will be used to help maintain the EIA–8A frame, eliminate duplicative reporting on Form EIA–7A and reduce burden between Forms EIA–8A and EIA–7A.

Form EIA–7A: Annual Survey of Coal Production and Preparation

- In Part 5, question 7, revise reporting categories of coal mine sales to simplify question wording while adding export categories to include open market export sales, captive market export sales, and broker export sales. The new categories will provide more accurate information on coal exports by type of sale and seller by eliminating potential double-counting of export coal sales on Form EIA–8A. It will improve EIAs assessments on production trends and coal supply by basin. It will also facilitate EIA's comparison of coal supply by basin with export data collected by the U.S. Census Bureau.

EIA proposes adding the following questions to Form EIA–7A:

- In Part 3, Question 5A, add the question *"What is the average depth of the mine below the surface?"* This question will assist with data discrepancies of coalbed data reported by comparing coalbeds mined with U.S. Geological Survey data.
- In Part 5, delete question 2 *"With the existing equipment in place, what is the maximum amount of coal that this mining operation can produce during the reporting year?"* and add *"With the existing equipment in place, what is the annual operating capacity of this mine?"* This is a rewording to the current question requesting annual operating/producing capacity. By comparing actual production compared to operating capacity, EIA can assess if mines are producing at maximum capacity and can use this as an indicator of market conditions affecting coal supply.
- In Part 5, delete question 5 *"As of December 31st of the reporting year, what is the estimated tonnage representing the amount of coal identified in the reserve that is technologically and economically feasible to extract?"* and add *"As of December 31st of the reporting year, what is the estimated amount of coal in the reserve that is feasible (economically/technologically) to extract?* This rewording of the current question requesting recoverable coal reserves helps clarify to respondents to report the amount of coal that can be recovered from the coal reserve in place.

Form EIA–8A: Annual Survey of Coal Stocks and Coal Exports

- In Part 2, Question 2, revise list of locations where U.S. produced coal stocks are located to include "IT—In Transit"
- In Part 3, Question 2, add new field requesting port of export and destination country for export sales to gather more detailed export data and assist in cross-survey comparison with the EIA–7A and coal trade data collected by the U.S. Census Bureau to quantify and eliminate double-counting of export coal sales.

Standby Forms EIA–6: Emergency Coal Supply Survey (Standby) and EIA–20: Emergency Weekly Coal Monitoring Survey for Coal Burning Power Producers (Standby)

- No substantive changes will be made to these forms.

Request for Comments: As a potential respondent to the request for information, review the proposed changes mentioned above, the survey forms and instructions, and please advise the following:

- Is the proposed collection of information necessary for the proper performance of the functions of the agency and does the information have practical utility?
- What actions could be taken to help ensure and maximize the quality, objectivity, utility, and integrity of the information to be collected?
- Are the instructions and definitions clear and sufficient? If not, which instructions need clarification?
- Can the information be submitted by the respondent by the due date?
- Can information be submitted using the proposed collection method?

(5) Estimated Number of Survey Respondents: 2,429.

- EIA–3 will consist of 432 respondents
- EIA–7A will consist of 848 respondents
- EIA–8A will consist of 48 respondents
- EIA–6 (standby) will consist of 610 respondents
- EIA–20 (standby) will consist of 491 respondents

(6) Annual Estimated Number of Responses: 3,725.

(7) Annual Estimated Number of Burden Hours: 5,515.

(8) Annual Estimated Reporting and Recordkeeping Cost Burden: Additional costs to respondents are not anticipated beyond costs associated with response burden hours. The information is maintained in the normal course of business. The cost of the burden hours is estimated to be $397,190 (5,515 burden hours times $72.02 per hour). Other than the cost of burden hours, EIA estimates that there are no additional costs for generating, maintaining and providing the information.

Statutory Authority: Section 13(b) of the Federal Energy Administration Act of 1974, Pub. L. 93–275, codified at 15 U.S.C. 772(b), and the DOE Organization Act of 1977, Pub. L. 95–91, codified at 42 U.S.C. 7101 *et seq.*

Issued in Washington, DC, on September 9, 2016.

Renee Miller,

Acting Director, Office of Survey Development and Statistical Integration, U.S. Energy Information Administration.

[FR Doc. 2016–22310 Filed 9–15–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2520–076]

Great Lakes Hydro America, LLC; Notice of Application Tendered for Filing With the Commission and Establishing Procedural Schedule for Licensing and Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. Project No.: 2520–076.

c. *Date Filed:* August 31, 2016.

d. *Applicant:* Great Lakes Hydro America, LLC (Great Lakes Hydro).

e. *Name of Project:* Mattaceunk Hydroelectric Project.

f. *Location:* The existing project is located on the Penobscot River in Aroostook and Penobscot Counties, Maine. The project does not affect federal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Kevin Bernier, Senior Compliance Specialist, Great Lakes Hydro America, LLC, 1024

Central Street, Millinocket, Maine 04462; Telephone (207) 723–4341, x118.

i. *FERC Contact:* Adam Peer, (202) 502–8449 or *adam.peer@ferc.gov.*

j. This application is not ready for environmental analysis at this time.

k. *The Project Description:* The existing Mattaceunk Hydroelectric Project consists of: (1) A 1,060-foot-long, 45-foot-high dam (Weldon Dam) with a crest elevation of 236.0 feet (USGS datum), and includes (i) a 110-foot-long earthen embankment extending to the left abutment; (ii) a combined intake and powerhouse structure; (iii) an upstream fish ladder; (iv) a 10-foot-wide log sluice structure, controlled by an 8-foot-high vertical slide gate; (v) a 90-foot-long, 19-foot-high gated spillway with a single roller gate; (vi) a 657.5-foot-long, 70-foot high concrete gravity overflow spillway with 4-foot-high flashboards to create a maximum flashboard crest elevation of 240.0 feet; and (vii) a retaining wall at the right abutment; (2) a 1,664-acre reservoir with a total storage capacity of 20,981 acre-feet at a normal pool elevation of 240.00 feet (USGS datum); (3) a 142-foot-long, 99-foot-wide powerhouse (Weldon Station) integral to the dam containing two Kaplan turbines rated at 5,479 kilowatt (kW) and two fixed-blade propeller turbines rated at 5,489 kW, each driving a 6,000 kilovolt-ampere (kVA), 4,800 kW vertical synchronous generator for an authorized installed capacity of 19.2 megawatts (MW); (4) a downstream fishway; (5) an outdoor substation adjacent to the powerhouse; (6) a 9-mile-long, 34.5-kilovolt (kV) transmission line within a 120-foot-wide right of way; and (7) appurtenant facilities. The project generates about 123,332 megawatt-hours (MWh) annually.

The Mattaceunk Project is operated with minimal fluctuations of the reservoir surface elevation. Flexibility on reservoir elevations is required to provide for safe installation of the project's flashboards and to allow an adequate margin for wave action, debris loads, or sudden pool increases that might cause flashboard failure. The existing license requires a reservoir surface elevation no lower than 1.0 foot below the dam crest elevation of 236.0 feet when the 4-foot-high flashboards are not in use, and no lower than 2.0 feet below the top of flashboard elevation of 240.0 feet when the 4-foot-high flashboards are in use. The existing license also requires a year-round continuous minimum flow of 1,674 cubic feet per second (cfs) or inflow, whichever is less, and a daily average minimum flow of 2,392 cfs from July 1 through September 30 and 2,000 cfs from October 1 through June 30, unless inflow is less than the stated daily average minimum flows (in which case outflow from the project must equal the inflow to the project). Great Lakes Hydro proposes to: (1) Install a seasonal upstream eel ramp; (2) install an upstream passage structure for American shad, alewife, and blueback herring; (3) install trashracks having 1-inch clear spacing to the full depth of the turbine intakes during the fish passage season; and (4) improve the recreation facility at the downstream angler access area.

l. *Locations of the Application:* A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). A copy is also available for inspection and reproduction at the address in item (h) above.

m. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. *Procedural Schedule:* The application will be processed according to the following preliminary Hydro Licensing Schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Notice of Acceptance/Notice of Ready for Environmental Analysis	October 2016.
Filing of recommendations, preliminary terms and conditions, and fishway prescriptions	December 2016.
Commission issues Draft Environmental Assessment (EA)	June 2017.
Comments on Draft EA	July 2017.
Modified terms and conditions	September 2017.
Commission issues Final EA	December 2017.

o. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: September 8, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–22266 Filed 9–15–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commission Staff Attendance at MISO Meetings

The Federal Energy Regulatory Commission (Commission) hereby gives notice that Commission staff may attend the following MISO-related meetings:

- Advisory Committee
  - September 14, 10:15 a.m.–3 p.m., St. Paul Hotel, 350 Market Street, St. Paul, MN
- Board of Directors Audit & Finance Committee
  - September 14, 3:45 p.m.–5 p.m., St. Paul Hotel, 350 Market Street, St. Paul, MN
- Board of Directors
  - September 15, 8:30 a.m.–12 noon, St. Paul Hotel, 350 Market Street, St. Paul, MN
- Board of Directors Markets Committee
  - September 13, 9 a.m.–12 noon, St. Paul Hotel, 350 Market Street, St. Paul, MN
- Board of Directors Corporate Governance and Strategic Planning Committee
  - September 13, 11:15 a.m.–1 p.m., St. Paul Hotel, 350 Market Street, St. Paul, MN

Unless otherwise noted all of the meetings above will be held at either:

Carmel, MISO Headquarters, 701 City Center Drive, 720 City Center Drive, and Carmel, IN 46032.

Little Rock, 1700 Centerview Drive, Little Rock, AR.
Eagan, 2985 Ames Crossing Rd., Eagan, MN.
Metarie, 3850 N. Causeway Blvd., Suite 442 Metairie, LA.

Further information and dial in instructions may be found at *www.misoenergy.org.* All times are Local Prevailing Time.

The above-referenced meetings are open to the public.

The discussions at each of the meetings described above may address matters at issue in the following proceedings:

Docket No. ER11–4081, *Midwest Independent Transmission System Operator, Inc.*
Docket No. ER12–678, *Midwest Independent Transmission System Operator, Inc.*
Docket No. ER12–2302, *Midwest Independent Transmission System Operator, Inc.*
Docket No. ER13–187, *Midwest Independent Transmission System Operator, Inc.*
Docket No. ER13–186, *Midwest Independent Transmission System Operator, Inc.*
Docket No. ER13–101, *Midwest Independent Transmission System Operator, Inc.*
Docket No. ER13–89, *MidAmerican Energy Company*
Docket No. ER12–1266, *Midwest Independent Transmission System Operator, Inc.*
Docket No. ER12–1265, *Midwest Independent Transmission System Operator, Inc.*
Docket No. ER13–1924, *Midcontinent Independent System Operator, Inc.*
Docket No. ER13–1943, *Midcontinent Independent System Operator, Inc.*
Docket No. ER13–1944, *Midcontinent Independent System Operator, Inc.*
Docket No. ER13–1945, *Midcontinent Independent System Operator, Inc.*
Docket No. EL13–88, *Northern Indiana Public Service Corp.* v *Midcontinent Independent System Operator, Inc., et al.*
Docket No. EL14–12, *ABATE et al.* v *Midcontinent Independent System Operator, Inc., et al.*
Docket No. AD12–16, *Capacity Deliverability across the MISO/PJM Seam*
Docket No. AD14–3, *Coordination of Energy and Capacity across the MISO/PJM Seam*
Docket No. ER13–1938, *Midcontinent Independent System Operator, Inc.*
Docket No. ER14–1736, *Midcontinent Independent System Operator, Inc.*
Docket No. ER14–2445, *Midcontinent Independent System Operator, Inc.*
Docket No. ER15–133, *Midcontinent Independent System Operator, Inc.*
Docket No. ER15–530, *Midcontinent Independent System Operator, Inc.*
Docket No. ER15–767, *Midcontinent Independent System Operator, Inc.*
Docket No. ER15–945, *Midcontinent Independent System Operator, Inc.*
Docket No. ER09–1431, *Midwest Independent Transmission System Operator, Inc.*
Docket No. ER11–2275, *Midwest Independent Transmission System Operator, Inc.*
Docket No. ER11–3279, *Midwest Independent Transmission System Operator, Inc.*
Docket No. ER12–1194, *Midwest Independent Transmission System Operator, Inc.*
Docket No. ER15–1210, *Midcontinent Independent System Operator, Inc.*
Docket No. ER13–1938, *Midcontinent Independent System Operator, Inc.*
Docket No. ER14–649, *Midcontinent Independent System Operator, Inc.*
Docket No. ER14–2952, *Midcontinent Independent System Operator, Inc.*
Docket No. ER14–2605, *Midcontinent Independent System Operator, Inc.*
Docket No. ER14–1210, *Midcontinent Independent System Operator, Inc.*
Docket No. ER15–943, *Midcontinent Independent System Operator, Inc.*
Docket No. ER16–469, *Midcontinent Independent System Operator, Inc.*
Docket No. ER15–2657, *Midcontinent Independent System Operator, Inc.*
Docket No. ER16–533, *Midcontinent Independent System Operator, Inc.*
Docket No. ER16–534, *Midcontinent Independent System Operator, Inc.*
Docket No. ER16–675, *Midcontinent Independent System Operator, Inc.*
Docket No. EL15–70, *Public Citizen, Inc* v. *Midcontinent Independent System Operator, Inc.*
Docket No. EL15–71, *People of the State of Illinois* v. *Midcontinent Independent System Operator, Inc.*
Docket No. EL15–72, *Southwestern Electric Cooperative, Inc.* v. *Midcontinent Independent System Operator, Inc.*
Docket No. EL15–82, *Illinois Industrial Energy Consumers* v. *Midcontinent Independent System Operator, Inc.*
Docket No. ER16–696, *Midcontinent Independent System Operator, Inc.*
Docket No. ER16–770, *Midcontinent Independent System Operator, Inc.*
Docket No. ER16–833, *Midcontinent Independent System Operator, Inc.*
Docket No. ER16–56, *Midcontinent Independent System Operator, Inc.*
Docket No. ER16–1039, *Midcontinent Independent System Operator, Inc.*
Docket No. ER16–1096, *Midcontinent Independent System Operator, Inc.*
Docket No. EL16–112, *Coalition of MISO Transmission Customers* v. *Midcontinent Independent System Operator, Inc.*

For more information, contact Patrick Clarey, Office of Energy Markets Regulation, Federal Energy Regulatory Commission at (317) 249–5937 or *patrick.clarey@ferc.gov,* or Christopher Miller, Office of Energy Markets Regulation, Federal Energy Regulatory Commission at (317) 249–5936 or *christopher.miller@ferc.gov.*

Dated: September 8, 2016.

Kimberly D. Bose,
Secretary.

[FR Doc. 2016–22265 Filed 9–15–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–71–000]

Notice of Institution of Section 206 Proceeding and Refund Effective Date

Monongahela Power Company
Potomac Edison Company
West Penn Power Company
AEP Indiana Michigan Transmission Company, Inc.
AEP Kentucky Transmission Company, Inc.
AEP Ohio Transmission Company, Inc.
AEP West Virginia Transmission Company, Inc.
Appalachian Power Company
Indiana Michigan Power Company
Kentucky Power Company
Kingsport Power Company
Ohio Power Company
Wheeling Power Company
Commonwealth Edison Company
Commonwealth Edison Company of Indiana, Inc.
Dayton Power and Light Company
Virginia Electric and Power Company
Public Service Electric and Gas Company
PECO Energy Company
PPL Electric Utilities Corporation
Baltimore Gas and Electric Company
Jersey Central Power & Light Company
Metropolitan Edison Company
Pennsylvania Electric Company
Potomac Electric Power Company
Atlantic City Electric Company
Delmarva Power & Light Company
UGI Utilities Inc.
Allegheny Electric Cooperative, Inc.
CED Rock Springs, LLC
Old Dominion Electric Cooperative
Rockland Electric Company
Duquesne Light Company
Neptune Regional Transmission System, LLC
Trans-Allegheny Interstate Line Company
Linden VFT, LLC
American Transmission Systems, Incorporated
City of Cleveland, Department of Public Utilities, Division of Cleveland Public Power

Duke Energy Ohio, Inc.
Duke Energy Kentucky, Inc.
City of Hamilton, OH
Hudson Transmission Partners, LLC
East Kentucky Power Cooperative, Inc.
City of Rochelle
ITC Interconnection LLC
PJM Interconnection, L.L.C.

On August 26, 2016, the Commission issued an order in Docket No. EL16–71–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2012), instituting an investigation into whether the PJM Transmission Owners are complying with their Order No. 890 obligations. *Monongahela Power Company et al.*, 156 FERC ¶ 61,134 (2016).

The refund effective date in Docket No. EL16–71–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in Docket No. EL16–71–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214, within 21 days of the date of issuance of the order.

Dated: September 8, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–22264 Filed 9–15–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP16–98–000; PF15–29–000]

Dominion Carolina Gas Transmission, LLC; Notice of Revised Schedule for Environmental Review of the Transco to Charleston Project

This notice identifies the Federal Energy Regulatory Commission staff's revised schedule for the completion of the Environmental Assessment (EA) for Dominion Carolina Gas Transmission, LLC's Transco to Charleston Project. The previous Notice of Schedule, issued on July 25, 2016, identified September 19, 2016 as the EA issuance date. However, Dominion Carolina Gas Transmission, LLC filed a supplement on August 22, 2016 which identified several route adjustments and workspace modifications. As a result, staff has revised the schedule for issuance of the EA.

Schedule for Environmental Review

Issuance of EA: October 19, 2016.
90-day Federal Authorization Decision Deadline: January 17, 2017.

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the project's progress.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of all formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription (*www.ferc.gov/docs-filing/esubscription.asp*).

Dated: September 8, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–22259 Filed 9–15–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ID–7993–000]

Van Orden, Tracy; Notice of Filing

Take notice that on September 7, 2016, Tracy Van Orden filed an application for authorization to hold interlocking positions, pursuant to section 305(b) of the Federal Power Act, 16 U.S.C. 825d(b), and Part 45 of the Regulations of the Federal Energy Regulatory Commission (Commission), 18 CFR Part 45.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on September 28, 2016.

Dated: September 8, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–22262 Filed 9–15–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commission Staff Attendance

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of the Commission's staff may attend the following meetings related to the transmission planning activities of the PJM Interconnection, L.L.C. (PJM):

PJM Planning Committee

September 15, 2016, 9:30 a.m.–12:00 p.m. (EST)

PJM Transmission Expansion Advisory Committee

September 15, 2016, 11:00 a.m.–3:00 p.m. (EST)

The above-referenced meetings will be held at:

PJM Conference and Training Center, PJM Interconnection, 2750 Monroe Boulevard, Audubon, PA 19403.

The above-referenced meetings are open to stakeholders. Further information may be found at *www.pjm.com.*

The discussions at the meetings described above may address matters at issue in the following proceedings:

Docket No. ER16–453, *PJM Interconnection, L.L.C. and Northeast Transmission Development, LLC.*
Docket No. ER16–736, *PJM Interconnection, L.L.C.*
Docket No. ER14–972, *PJM Interconnection, L.L.C.*

Docket No. ER14–1485, *PJM Interconnection, L.L.C.*

Docket Nos. ER13–1944, *et al., PJM Interconnection, L.L.C., et al.*

Docket No. ER15–1344, *PJM Interconnection, L.L.C.*

Docket No. ER15–1387, *PJM Interconnection, L.L.C. and Potomac Electric Power Company*

Docket No. ER15–2562, *PJM Interconnection, L.L.C.*

Docket No. ER15–2563, *PJM Interconnection, L.L.C.*

Docket No. EL15–18, *Consolidated Edison Company of New York, Inc.* v. *PJM Interconnection, L.L.C.*

Docket No. EL15–41, *Essential Power Rock Springs, L.L.C., et al.* v. *PJM Interconnection, L.L.C.*

Docket No. ER15–2114, *PJM Interconnection, L.L.C. and Transource West Virginia, L.L.C.*

Docket No. EL15–79, *TransSource, L.L.C.* v. *PJM Interconnection, L.L.C.*

Docket No. EL15–95, *Delaware Public Service Commission, et al.,* v. *PJM Interconnection, L.L.C., et al.*

Docket No. EL15–67, *Linden VFT, L.L.C.* v. *PJM Interconnection, L.L.C.*

Docket No. EL05–121, *PJM Interconnection, L.L.C.*

Docket No. ER13–198, *PJM Interconnection, L.L.C.*

Docket No. ER16–1335, *PJM Interconnection, L.L.C.*

Docket No. ER16–1232, *PJM Interconnection, L.L.C.*

Docket No. ER16–1499, *PJM Interconnection, L.L.C.*

Docket No. ER16–1807, *First Energy Solutions Corp.*

Docket No. EL16–96, *PJM Interconnection, L.L.C.*

Docket No. EL16–71, *Monongahela Power Company et al.*

Docket No. ER16–2518, *PJM Interconnection, L.L.C.*

Docket No. ER16–2539, *PJM Interconnection, L.L.C.*

Docket No. ER16–2401, *PJM Interconnection, L.L.C.*

Docket No. EL16–109–000, *Virginia Electric and Power Company* v. *PJM Interconnection L.L.C.*

For more information, contact the following:

Jonathan Fernandez, Office of Energy Market Regulation, Federal Energy Regulatory Commission, (202) 502–6604, *Jonathan.Fernandez@ferc.gov.*

Alina Halay, Office of Energy Market Regulation, Federal Energy Regulatory Commission, (202) 502–6474, *Alina.Halay@ferc.gov.*

Dated: September 7, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–22267 Filed 9–15–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–497–000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization

Take notice that on August 29, 2016, Columbia Gas Transmission, LLC (Columbia), 5151 San Felipe, Suite 2500, Houston, Texas 77056, filed in Docket No. CP16–497–000, a prior notice request pursuant to sections 157.205, 157.213, and 157.216 of the Commission's regulations under the Natural Gas Act (NGA). Columbia seeks authorization to: (i) Convert a storage well in Wayne County, Ohio from injection/withdrawal status to observation status and abandon its associated pipeline and appurtenances, and (ii) plug and abandon two storage wells, and their associated appurtenances, located in Ashland, and Vinton Counties, Ohio, respectively. Columbia proposes to perform these activities under its blanket certificate issued in Docket No. CP83–76–000, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The filing may be viewed on the web at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions regarding this application should be directed to William A. Sala, Jr., Senior Counsel, Columbia Gas Transmission, LLC, 5151 San Felipe, Suite 2500, Houston, Texas 77056, or by calling (713) 386–3743 (telephone), or (713) 386–3755 (fax) *tsala@cpg.com.*

Any person or the Commission's Staff may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and, pursuant to section 157.205 of the Commission's Regulations under the NGA (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the Internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*www.ferc.gov*) under the "e-Filing" link. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Dated: September 8, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–22260 Filed 9–15–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR16–20–000]

ITC Pipeline Company, LLC; Notice of Request for Waiver

Take notice that on July 14, 2016, pursuant to Rule 207(a)(5) of the Federal Energy Regulatory Commission's (Commission), ITC Pipeline Company, LLC ("ITC Pipeline") requests waiver of the portion of 18 CFR 342.4(c)(2016), that would require ITC Pipeline to submit a verified statement in support of (1) the incentive rates ("Incentive Rates") agreed to by ITC Pipeline's current shippers, as opposed to its prospective shippers who will begin shipping once ITC Pipeline goes into service, and (2) any changes to the Incentive Rates that ITC Pipeline makes in a subsequent tariff filing with the Commission provided such changes are made in accordance with the written terms of the applicable dedication agreement described in the transmittal letter of ITC Pipeline's initial rules and rates tariff filed concurrently therewith.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214 (2014)) on or before 5:00 p.m. Eastern time on the specified comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on September 23, 2016.

Dated: September 8, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–22263 Filed 9–15–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–112–000]

Coalition of MISO Transmission Customers v. Midcontinent Independent System Operator, Inc.; Notice of Complaint

Take notice that on September 8, 2016, pursuant to sections 206, 306, and 309 of the Federal Power Act, 16 U.S.C. 824e, 825e, and 825h (2012), and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206 (2014), the Coalition of MISO Transmission Customers (Complainant) filed a formal complaint against Midcontinent Independent System Operator, Inc. (MISO or Respondent) alleging that Respondent's calculation of the export limit for the 2016–2017 Planning Resource Auction from the MISO South region to the MISO Midwest region was unjust and unreasonable, all as more fully explained in the complaint.

Complainant states that copies of the complaint were served on the contacts for Respondent listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on September 28, 2016.

Dated: September 8, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–22261 Filed 9–15–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2307–078]

Alaska Electric Light & Power Company; Notice of Application Tendered for Filing With the Commission and Soliciting Study Requests and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Major Subsequent License.

b. *Project No.:* 2307–078.

c. *Date filed:* August 31, 2016.

d. *Applicant:* Alaska Electric Light and Power Company.

e. *Name of Project:* Salmon and Annex Creek Hydroelectric Project.

f. *Location:* On Salmon Creek and Annex Creek in the City and Borough of Juneau, Alaska. The project occupies about 648.45 acres of federal lands located in the Tongass National Forest administered by the United States Forest Service and operates under an existing license issued in 1988.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Christy Yearous, Project Manager, Alaska Electric Light & Power Company, 5601 Tongsard Ct., Juneau, AK 99801–7201; (907) 780–2222.

i. *FERC Contact:* Suzanne Novak at (202) 502–6665, *Suzanne.novak@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See,* 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. Deadline for filing additional study requests and requests for cooperating agency status: October 31, 2016.

The Commission strongly encourages electronic filing. Please file requests for cooperating agency status using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–2307–078.

m. The application is not ready for environmental analysis at this time.

n. The proposed Salmon and Annex Creek Project consists of two developments, one on Salmon Creek and one on Annex Creek.

The Salmon Creek development consists of the following existing facilities: (1) The 165-acre Salmon Creek reservoir impounded by a 648-foot-long, 168-foot-high dam, with ten 5-foot-wide spillway bays; (2) a 1,500-foot-long segment of a canal used to periodically divert water from tributary streams into Salmon Creek Reservoir; (3) a 10-foot-wide, 11-foot-high intake structure with trashracks at the base of the dam; (4) a 3-foot-diameter conduit that conveys flows from the dam to the project valvehouse located immediately downstream; (5) the project valvehouse containing two penstocks: (i) An 11,030-foot-long, 3.5-foot-diameter penstock that narrows to a 2.5-foot-diameter immediately before entering the Lower Powerhouse, and (ii) a 4,290-foot-long, 3.3- to-2.5-foot-diameter penstock that conveys flows to the decommissioned Upper Powerhouse; (6) the 57-foot-long, 44-foot-wide, 32-foot-high, Lower Powerhouse, which contains a 6.9-megawatt (MW) impulse turbine; (7) an approximately 250-foot-long tailrace that flows underneath Egan Drive and empties into a pond adjacent to the Douglas Island Pink and Chum, Inc., hatchery; and (8) appurtenant facilities.

The Annex Creek development consists of the following existing facilities: (1) The 264-acre Upper Annex Lake, impounded by a 118-foot-long, 20-foot-high dam with a 57-foot-wide spillway that discharges flows in excess of those needed for generation into the Lower Annex Lake; (2) a small timber saddle dam, 61 feet long and 6 feet high, located just west of the main dam; (3) the natural 27-acre Lower Annex Lake; (4) a lake tap intake on Upper Annex Lake; (5) a 1,433-foot-long power tunnel that narrows from 8 feet wide and 8 feet high at the intake to a 6.5-foot-diameter tunnel at the project valvehouse; (6) the project valvehouse containing the penstock intake; (7) the 7,097-foot-long, 3.5-foot-diameter penstock that narrows to a 2.8-foot-diameter before it bifurcates at the powerhouse to provide flows to two impulse turbine units with a total installed capacity of 3.675 MW; (8) the 67-foot-long, 48-foot-wide, 40-foot-high, powerhouse; (9) a tailrace that discharges flows over a weir into Taku Inlet; (10) a 12.5-mile-long, 23-kilovolt (kV) transmission line that conveys power to the Thane substation; and (11) appurtenant facilities.

The project currently operates to provide base load generation with an estimated annual output of 53.8 gigawatt-hours. No changes to project operation or facilities are proposed.

o. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. *Procedural schedule:* The application will be processed according to the following preliminary Hydro Licensing Schedule. Revisions to the schedule will be made as appropriate.

Issue Notice of Acceptance	November 2016.
Issue Scoping Document 1	December 2016.
Comments on Scoping Document 1	January 2017.
Issue Scoping Document 2	March 2017.
Issue Notice Ready for Environmental Analysis	March 2017.
Filing of Comments, Terms and Conditions, Recommendations and Prescriptions	June 2017.
Applicant's reply comments	August 2017.
Commission issues Environmental Assessment (EA)	November 2017.
Comments on draft EA	December 2017.

Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: September 9, 2016.

Kimberly D. Bose,

Secretary.

[FR Doc. 2016–22268 Filed 9–15–16; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2016–0094–1138; FRL–9952–38–OAR]

Agency Information Collection Activities; Proposed Collection; Comment Request; Information Collection for Importation of On-Highway Vehicles and Motorcycles and Nonroad Engines, Vehicles, and Equipment; EPA ICR Number 2583.01, OMB Control Number 2060—NEW

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit an Information Collection Request (ICR) for the information requirements for importation of on-highway vehicles and motorcycles and nonroad engines, vehicles, and equipment to the Office of Management and Budget (OMB). This new ICR is the consolidation of two individual ICRS that are currently approved by OMB. EPA currently has an approved collection that covers the information requirements for importation of on-highway vehicles which expires on October 31, 2016 (OMB Control Number 2060–0095, ICR Number 0010.14). EPA also has an approved collection for information requirements for importation of nonroad engines and recreational vehicles (OMB Control Number 2060–0320, ICR Number 1723.07), which expires February 28, 2017. Before submitting this new ICR to OMB for review and approval, EPA is soliciting comments on the proposed information collection as described below.

DATES: Comments must be submitted on or before November 15, 2016.

ADDRESSES: Submit your comments referencing Docket ID No. EPA–HQ–OAR–2016–0094 online using *www.regulations.gov* (our preferred method), by email to *pugliese.holly@epa.gov* or by mail to: EPA Docket Center, Environmental Protection Agency, Mailcode 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Holly Pugliese, Compliance Division, Office of Transportation and Air Quality, Environmental Protection Agency, 2000 Traverwood, Ann Arbor, Michigan, 48105; telephone number: 734–214–4288; fax number: 734–214–4869; email address: *pugliese.holly@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: This ICR will consolidate two separate ICRs that currently individually cover EPA Declaration Forms 3520–1, 3520–21, and 3520–8. EPA Declaration Form 3520–1 is used by importers of on-highway vehicles and motorcycles and EPA Declaration Form 3520–21 is used by importers of nonroad vehicles, engines and equipment to help facilitate importation of products at U.S. Borders. Each form identifies the regulated category of engine or vehicle and the regulatory provisions under which the importation is taking place. In addition, this ICR covers the burden of EPA Form 3520–8 which is used to request final importation clearance for Independent Commercial Importers (ICIs) of on-highway vehicles who are required to bring the on-highway vehicles into compliance and provide test results. This form is currently covered by OMB 2060–0095. EPA is consolidating these two ICRS due to the effort being undertaken by the U.S. Customs and Border Protection to require electronic filing for all importers. Over the last several years, CBP has been developing the Automated Commercial Environment (ACE) for electronic filing. By the end of 2016, ACE will become the primary system the trade community and other importers will use to report imports and exports. Through ACE as the single window, manual processes will be streamlined and automated, and paper submissions (*e.g.* fillable PDFs) will essentially be eliminated. However, EPA will continue to maintain the forms on our Web site in fillable PDF format.

EPA does not collect the forms, but rather makes them available to importers and CBP to facilitate entry of goods at the port. EPA may ask for them upon request to assist CPB and/or EPA enforcement personnel for any given import for which there are questions or issues. The forms are primarily used by CBP at the time of importation to assist CBP in making determination if entry should be allowed. CBP regulations require that the forms be submitted as applicable at the time of entry; see 19 CFR 12.73 and 12.74.

Form Numbers: 3520–1, 3520–21, 3520–8.

Frequency of response: Once per entry. (One form per shipment may be used.)

Respondents/affected entities: Information collected is from individual importers, or companies who import and/or manufacture on-highway vehicles and nonroad engines, vehicles, and equipment.

Respondent's obligation to respond: Required for any importer to legally import nonroad vehicles or engines into the U.S.

Estimated number of respondents: 14,810.

Total estimated burden: 13,985 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $513,633 (per year), includes $48,064 annualized capital or operation & maintenance costs.

Changes in Estimates: EPA is establishing new burden estimates as we combine the burden estimates for the two separate ICRs that currently cover the forms.

Dated: September 8, 2016.

Byron J. Bunker,

Director, Compliance Division, Office of Transportation and Air Quality.

[FR Doc. 2016–22219 Filed 9–15–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9029–1]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EISs)

Filed 09/05/2016 Through 09/09/2016

Pursuant to 40 CFR 1506.9.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

EIS No. 20160206, Final, AFS, CA, Los Padres Tamarisk Removal, Review Period Ends: 10/26/2016, Contact: Kyle Kinports 805–961–5710.

EIS No. 20160207, Final, USACE, NY, South Shore of Staten Island Coastal Storm Risk Management, Review Period Ends: 10/17/2016, Contact: Catherine J. Alcoba 917–790–8216.

EIS No. 20160208, Final Supplement, BOEM, LA, Gulf of Mexico OCS Oil and Gas Lease Sale: 2017 Central Planning Area Lease Sale 247 Review Period Ends: 10/17/2016, Contact: Gary Goeke 504–736ndash;3233.

EIS No. 20160209, Draft, DOC, AZ, Programmatic—West Region of the Nationwide Public Safety Broadband Network, Comment Period Ends: 11/15/2016, Contact: Genevieve Walker 571–665–6134.

EIS No. 20160210, Final, USFS, CA Lassen National Forest Over-Snow Vehicle (OSV) Use Designation, Review Period Ends: 10/17/2016, Contact: Christopher O'Brien 530–262–6698.

Amended Notices

EIS No. 20160176, Draft, USACE, NY, Fire Island Inlet to Montauk Point, New York Combined Beach Erosion Control and Hurricane Protection Project, Comment Period Ends: 10/19/2016, Contact: Robert Smith 917–790–8729.

Revision to FR Notice published 07/29/2016; extending comment period from 09/29/2016 to 10/19/2016.

Dated: September 13, 2016.

Dawn Roberts,

Management Analyst, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2016–22362 Filed 9–15–16; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK OF THE UNITED STATES

Notice of Open Meeting of the Advisory Committee of the Export-Import Bank of the United States (Ex-Im Bank)

SUMMARY: The Advisory Committee was established by Public Law 98–181, November 30, 1983, to advise the Export-Import Bank on its programs and to provide comments for inclusion in the report on competitiveness of the Export-Import Bank of the United States to Congress.

TIME AND PLACE: Wednesday, September 28, 2016 from 11:00 a.m.–3:00 p.m.. A break for lunch will be at the expense of the attendee. Security processing will be necessary for reentry into the building. The meeting will be held at EXIM Bank in the Main Conference Room—11th floor, 811 Vermont Avenue NW., Washington, DC 20571.

AGENDA: Discussion will focus on the Advisory Committee's final recommendations for EXIM Bank staff based on the Committee's work during this fiscal year. The Advisory Committee will also hear from external speakers and EXIM Bank officials.

PUBLIC PARTICIPATION: The meeting will be open to public participation, and 10 minutes will be set aside for oral questions or comments. Members of the public may also file written statement(s) before or after the meeting. If you plan to attend, a photo ID must be presented at the guard's desk as part of the clearance process into the building, you may contact Tia Pitt at *tia.pitt@exim.gov* to be placed on an attendee list. If any person wishes auxiliary aids (such as a sign language interpreter) or other special accommodations, please email Tia Pitt at *tia.pitt@exim.gov* prior to September 21, 2016.

MEMBERS OF THE PRESS: For members of the Press planning to attend the meeting, a photo ID must be presented at the guard's desk as part of the clearance process into the building please email Tia Pitt at *tia.pitt@exim.gov* to be placed on an attendee list.

FURTHER INFORMATION: For further information, contact Tia Pitt, 811 Vermont Ave. NW., Washington, DC 20571, at *tia.pitt@exim.gov*

Bonita Jones-McNeil,

Program Analyst, Agency Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2016–22330 Filed 9–15–16; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 3:30 p.m. on Tuesday, September 20, 2016, to consider the following matters:

SUMMARY AGENDA: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of minutes of previous Board of Directors' Meetings.

Memorandum and resolution re: Notice of Proposed Rulemaking: Establishing Restrictions on Qualified Financial Contracts of Certain FDIC-Supervised Institutions; Revisions to the Definition of Qualifying Master Netting Agreement and Related Definitions.

Memorandum and resolution re: Regulatory Capital Rules, Liquidity Coverage Ratio; Revisions to the Definition of Qualifying Master Netting Agreement and Related Definitions.

Memorandum and resolution re: Designated Reserve Ratio for 2017.

Summary reports, status reports, reports of the Office of Inspector General, and reports of actions taken pursuant to authority delegated by the Board of Directors.

DISCUSSION AGENDA: Update of Projected Deposit Insurance Fund Losses, Income, and Reserve Ratios for the Restoration Plan.

The meeting will be held in the Board Room located on the sixth floor of the FDIC Building located at 550 17th Street NW., Washington, DC.

This Board meeting will be Webcast live via the Internet and subsequently made available on-demand approximately one week after the event. Visit *http://fdic.windrosemedia.com* to view the event.

If you need any technical assistance, please visit our Video Help page at: *https://www.fdic.gov/video.html.*

The FDIC will provide attendees with auxiliary aids (*e.g.,* sign language interpretation) required for this meeting. Those attendees needing such assistance should call 703–562–2404 (Voice) or 703–649–4354 (Video Phone) to make necessary arrangements.

Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Executive Secretary of the Corporation, at 202–898–7043.

Dated: September 13, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–22436 Filed 9–14–16; 11:15 am]

BILLING CODE 6714–01–P

FEDERAL TRADE COMMISSION

Granting of Request for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register**.

The following transactions were granted early termination—on the dates indicated—of the waiting period provided by law and the premerger notification rules. The listing for each transaction includes the transaction number and the parties to the transaction. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

EARLY TERMINATIONS GRANTED

[August 1, 2016 thru August 31, 2016]

08/01/2016		
20161409	G	Elliott International Limited; LifeLock, Inc.; Elliott International Limited.
20161410	G	Elliott Associates, L.P.; LifeLock, Inc.; Elliott Associates, L.P.
20161463	G	Wolseley plc; Michael Butler; Wolseley plc.
20161482	G	Flextronics International Ltd.; Bose 2010 Special Purpose Trust; Flextronics International Ltd.
20161507	G	Lions Gate Entertainment Corp.; Starz; Lions Gate Entertainment Corp.
08/02/2016		
20161414	G	LSF9 Cypress LP; Superior Plus Corp.; LSF9 Cypress LP.
20161485	G	VGD Buyer, LLC; Frank Fertitta III; VGD Buyer, LLC.
20161486	G	VGD Buyer, LLC; Lorenzo Fertitta; VGD Buyer, LLC.
20161499	G	Wirecard AG; Citigroup Inc.; Wirecard AG.
20161514	G	Unilever N.V.; Dollar Shave Club, Inc.; Unilever N.V.
08/03/2016		
20161441	G	Nippon Paper Industries Co., Ltd.; Weyerhaeuser Co.; Nippon Paper Industries Co., Ltd.
08/04/2016		
20161240	G	International Paper Company; Weyerhaeuser Company; International Paper Company.
20161371	G	Chamly Aspen Trust; Axiall Corporation; Chamly Aspen Trust.
20161511	G	ISQ Global Infrastructure Fund, L.P.; Alcoa Inc.; ISQ Global Infrastructure Fund, L.P.
08/08/2016		
20151767	G	Konecranes Plc; Terex Corporation; Konecranes Plc.
20161037	G	Experian plc; Investcorp CSID Holdings, LLC; Experian plc.
20161451	G	Terex Corporation; Konecranes Plc; Terex Corporation.
20161508	G	Evolent Health, Inc.; Valence Health, Inc.; Evolent Health, Inc.
20161523	G	Headwaters Incorporated; William E. Robinson, Jr.; Headwaters Incorporated.
20161525	G	Triangle Private Investments, LLC; Polycom, Inc.; Triangle Private Investments, LLC.
20161526	G	Fidelity National Financial, Inc.; CINC Superior Holdings LLC; Fidelity National Financial, Inc.
20161527	G	EQT Midstream Partners, LP; EQT Corporation; EQT Midstream Partners, LP.
20161530	G	Halmont Properties Corporation; Energy Future Holdings Corp.; Halmont Properties Corporation.
20161531	G	Brookfield Capital Partners Fund III LP; Energy Future Holdings Corp.; Brookfield Capital Partners Fund III LP.
20161532	G	North Haven Infrastructure Partners II AIV–I L.P.; Randall Broda; North Haven Infrastructure Partners II AIV–I L.P.
20161536	G	AP VIII Aspen Holdings, L.P.; Outerwall Inc.; AP VIII Aspen Holdings, L.P.
20161540	G	AF IV Energy AIV B1, L.P.; Clayton Williams Energy, Inc.; AF IV Energy AIV B1, L.P.
20161551	G	Refresco Group N.V.; The Jerry Whitlock Living Trust; Refresco Group N.V.
08/09/2016		
20161462	G	KKR Element Aggregator L.P.; Eagle Topco LP; KKR Element Aggregator L.P.

EARLY TERMINATIONS GRANTED—Continued

[August 1, 2016 thru August 31, 2016]

20161476	G	Abrams Capital Partners II, L.P.; NorthStar Asset Management Group Inc.; Abrams Capital Partners II, L.P.
20161524	G	SAF-Holland S.A.; Haldex AB; SAF-Holland S.A.
20161537	G	Co-Investor 3 L.L.C.; NextEra Energy, Inc.; Co-Investor 3 L.L.C.
08/10/2016		
20161488	G	U.S. Silica Holdings, Inc.; New Birmingham, Inc.; U.S. Silica Holdings, Inc.
20161515	G	Susanne Klatten; Ovivo Inc.; Susanne Klatten.
08/11/2016		
20160865	G	Intercontinental Exchange, Inc.; McGraw Hill Financial, Inc.; Intercontinental Exchange, Inc.
08/12/2016		
20161492	G	Santen Pharmaceutical Co., Ltd.; InnFocus Inc.; Santen Pharmaceutical Co., Ltd.
20161521	G	Avast Holding B.V.; AVG Technologies N.V.; Avast Holding B.V.
20161544	G	Hainan Cihang Charitable Foundation; Marilyn Carlson Nelson 1998 GST Exempt Family Trust; Hainan Cihang Charitable Foundation.
20161545	G	Hainan Cihang Charitable Foundation; Barbara Carlson Gage 1998 GST Exempt Family Trust; Hainan Cihang Charitable Foundation.
20161553	G	SAS Rue La Boetie; Infra Foch Topco SAS; SAS Rue La Boetie.
20161555	G	salesforce.com, inc.; Quip, Inc.; salesforce.com, inc.
20161559	G	The Goldman Sachs Group, Inc.; Navico Holding AS; The Goldman Sachs Group, Inc.
20161560	G	Altor Holding AB; Navico Holding AS; Altor Holding AB.
20161561	G	Bret Taylor; salesforce.com, inc.; Bret Taylor.
20161562	G	Klondex Mines Ltd.; Waterton Precious Metals Fund II Cayman, LP; Klondex Mines Ltd.
20161564	G	TA XI L.P.; Robert D. and Gwendolyn A. Tyler; TA XI L.P.
20161566	G	G–III Apparel Group, Ltd.; Bernard Arnault; G–III Apparel Group, Ltd.
20161570	G	Platinum Equity Capital Partners III, L.P.; Fabcon Companies, LLC; Platinum Equity Capital Partners III, L.P.
20161573	G	KIA IX (Snow) Investor, L.P.; Phyllis R. Cretors; KIA IX (Snow) Investor, L.P.
20161575	G	Revelstoke Capital Partners Fund I, L.P.; Shore Capital Partners Fund IV, L.P.; Revelstoke Capital Partners Fund I, L.P.
20161581	G	Compass Diversified Holdings; TA X L.P.; Compass Diversified Holdings.
08/15/2016		
20161337	G	SLP IV Castle Feeder I, L.P.; Talent Holdings, LLC; SLP IV Castle Feeder I, L.P.
20161517	G	Gryphon Partners IV, L.P.; Carousel Capital Partners IV, L.P.; Gryphon Partners IV, L.P.
20161535	G	Nestle S.A.; Roche Holding Ltd.; Nestle S.A.
20161552	G	The Kroger Co.; ACP Investment Fund, L.P.; The Kroger Co.
20161556	G	EnCap Flatrock Midstream Fund II, L.P.; NGP Natural Resources X, L.P.; EnCap Flatrock Midstream Fund II, L.P.
20161557	G	Providence Equity Partners VI–A L.P.; Providence Equity Partners VI L.P.; Providence Equity Partners VI–A L.P.
20161567	G	U.S. Silica Holdings, Inc.; Sandy Creek Capital, LLC; U.S. Silica Holdings, Inc.
20161568	G	LeverageSource, L.P.; Energy Future Holdings Corp.; LeverageSource, L.P.
20161572	G	Q Super Holdings, Inc.; Roark Capital Partners II, LP; Q Super Holdings, Inc.
08/16/2016		
20161502	G	NewCo; 2003 TIL Settlement; NewCo.
20161578	G	Jaguar Holding Company I; STG IV, L.P.; Jaguar Holding Company I.
08/17/2016		
20161467	G	Agrium Inc.; Cargill, Incorporated; Agrium Inc.
08/19/2016		
20161580	G	Yong Wang; Toronto Oak Trust; Yong Wang.
20161590	G	Myriad Genetics, Inc.; Assurex Health, Inc.; Myriad Genetics, Inc.
20161592	G	ABRY Partners VIII, L.P.; American International Group, Inc.; ABRY Partners VIII, L.P.
20161595	G	Dentsu Inc.; Merkle Group Inc.; Dentsu Inc.
20161598	G	Nissha Printing Co., Ltd.; WestView Capital Partners II, L.P.; Nissha Printing Co., Ltd.
20161618	G	AP VIII Eagle LM5 Holdings, L.P.; Constellis Holdings, LLC; AP VIII Eagle LM5 Holdings, L.P.
08/22/2016		
20161604	G	Carlyle Partners VI, L.P.; Damien Lamendola; Carlyle Partners VI, L.P.
08/23/2016		
20161516	G	Smith & Wesson Holding Corporation; Crimson Trace Holdings, LLC; Smith & Wesson Holding Corporation.
20161574	G	OCP Trust; EPIQ Systems, Inc.; OCP Trust.
20161576	G	Harvest Partners VII, L.P.; OCP Trust; Harvest Partners VII, L.P.

EARLY TERMINATIONS GRANTED—Continued

[August 1, 2016 thru August 31, 2016]

20161603	G	Bridge Growth Partners, LP; Spectrum Equity Investors VI, L.P.; Bridge Growth Partners, LP.
08/24/2016		
20161605	G	PFS Holdings LLC; Big Bear Holdings Corp.; PFS Holdings LLC.
20161616	G	Tesla Motors, Inc.; SolarCity Corporation; Tesla Motors, Inc.
08/25/2016		
20161577	G	ScanSource, Inc.; Intelisys Communications, Inc.; ScanSource, Inc.
08/26/2016		
20161479	G	Henkel AG & Co. KGaA; Spotless Group Holding LLC; Henkel AG & Co. KGaA.
20161609	G	The Scotts Miracle-Gro Company; Treg C. Bradley; The Scotts Miracle-Gro Company.
20161613	G	NRG Energy, Inc.; SunEdison, Inc.; NRG Energy, Inc.
20161614	G	Steinhoff International Holdings N.V.; Mattress Firm Holding Corporation; Steinhoff International Holdings N.V.
20161622	G	Luigi Agrati; Monomoy Capital Partners II, L.P.; Luigi Agrati.
20161629	G	Hi-Crush Partners LP; Hi-Crush Proppants LLC; Hi-Crush Partners LP.
20161633	G	KKR North America Fund XI, L.P.; Calabrio, Inc.; KKR North America Fund XI, L.P.
20161636	G	FR XIII Foxtrot AIV, L.P.; Applied-Cleveland Holding Company, LLC; FR XIII Foxtrot AIV, L.P.
20161647	G	Investor AB; Audax Private Equity Fund III, L.P.; Investor AB.
20161648	G	Fortune Brands Home & Security, Inc.; Rohl, LLC; Fortune Brands Home & Security, Inc.
20161652	G	Aurora Equity Partners V L.P.; Solaray, LLC; Aurora Equity Partners V L.P.
20161659	G	Randstad Holding nv; Monster Worldwide, Inc.; Randstad Holding nv.
20161661	G	EQT VII (No. 1) Limited Partnership; Press Ganey Holdings, Inc.; EQT VII (No. 1) Limited Partnership.
08/30/2016		
20161588	G	Partners Group Access 871 L.P.; SMS–THL Holdings I, Inc.; Partners Group Access 871 L.P.
20161627	G	CenterOak Equity Fund I, L.P.; Levine Leichtman Capital Partners III, L.P.; CenterOak Equity Fund I, L.P.
20161634	G	KBR, Inc.; Honeywell International Inc.; KBR, Inc.
08/31/2016		
20161571	G	E*Trade Financial Corporation; General Atlantic Partners 96, L.P.; E*Trade Financial Corporation.
20161630	G	Warburg Pincus Private Equity XI, L.P.; Avalara, Inc.; Warburg Pincus Private Equity XI, L.P.
20161641	G	CCMP Capital Investors III, L.P.; Jerry Newman Carr; CCMP Capital Investors III, L.P.
20161643	G	CCMP Capital Investors III, L.P.; William Henry Carr; CCMP Capital Investors III, L.P.

For Further Information Contact: Theresa Kingsberry, Program Support Specialist, Federal Trade Commission Premerger Notification Office Bureau of Competition, Room CC–5301, Washington, DC 20024, (202) 326–3100.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–22282 Filed 9–15–16; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10527]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: The necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by October 17, 2016.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR,* Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number,

and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Annual Eligibility Redetermination, Product Discontinuation and Renewal Notices; *Use:* Section 1411(f)(1)(B) of the Affordable Care Act directs the Secretary of Health and Human Services (the Secretary) to establish procedures to redetermine the eligibility of individuals on a periodic basis in appropriate circumstances. Section 1321(a) of the Affordable Care Act provides authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of title I of the Affordable Care Act. Under section 2703 of the PHS Act, as added by the Affordable Care Act, and former section 2712 and section 2741 of the PHS Act, enacted by the Health Insurance Portability and Accountability Act of 1996, health insurance issuers in the group and individual markets must guarantee the renewability of coverage unless an exception applies. The final rule "Patient Protection and Affordable Care Act; Annual Eligibility Redeterminations for Exchange Participation and Insurance Affordability Programs; Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges" (79 FR 52994), provides that an Exchange may choose to conduct the annual redetermination process for a plan year (1) in accordance with the existing procedures described in 45 CFR 155.335; (2) in accordance with procedures described in guidance issued by the Secretary for the coverage year; or (3) using an alternative proposed by the Exchange and approved by the Secretary. The guidance document "Guidance on Annual Redeterminations and Re-enrollment for Marketplace Coverage for 2017" contains the procedures that the Secretary is specifying for the 2017 coverage year, as noted in (2) above. These procedures will be adopted by the Federally-facilitated Exchange. The final rule also amends the requirements for product renewal and re-enrollment (or non-renewal) notices to be sent by Qualified Health Plan (QHP) issuers in the Exchanges and specifies content for these notices. The accompanying guidance document "Updated Federal Standard Notices of Product Discontinuation and Renewal" provides standard notices for product discontinuation and renewal to be sent by issuers of individual market QHPs and issuers in the individual market. Issuers in the small group market may use the draft Federal standard small group notices released in the June 26, 2014 bulletin "Draft Standard Notices When Discontinuing or Renewing a Product in the Small Group or Individual Market", or any forms of the notice otherwise permitted by applicable laws and regulations. States that are enforcing the guaranteed renewability provisions of the Affordable Care Act may develop their own standard notices for product discontinuances, renewals, or both, provided the State-developed notices are at least as protective as the Federal standard notices. *Form Number:* CMS–10527 (OMB control number 0938–1254); *Frequency:* Annually; *Affected Public:* Private Sector, State Governments; *Number of Respondents:* 2,945; *Total Annual Responses:* 12,224; *Total Annual Hours:* 149,186. (For policy questions regarding this collection contact Russell Tipps at 301–492–4371).

Dated: September 13, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–22342 Filed 9–15–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Personal Responsibility Education Program (PREP) Performance Measures and Adult Preparation Subjects (PMAPS) Studies—Data Collection Related to the Performance Measures Study.

OMB No.: New Collection.

Description: The Office of Planning, Research, and Evaluation (HHS/ACF/OPRE) and the Family and Youth Services Bureau (HHS/ACF/ACYF/FYSB) in the Administration for Children and Families (ACF) propose a data collection activity as part of the Personal Responsibility Education Program (PREP) Performance Measures and Adult Preparation Subjects (PMAPS) Studies. The goals of the PMAPS studies are to collect, analyze, and report on performance measure data for PREP programs and to develop and test Adult Preparation Subjects (APS) conceptual models.

The PMAPS studies consist of two components: The "Performance Measures Study," and the "Adult Preparation Subjects Study." This notice is specific to data collection activities for the Performance Measures Study only. The Performance Measures Study component includes collection and analysis of performance measure data from State PREP (SPREP), Tribal PREP (TPREP), Competitive PREP (CPREP), and Personal Responsibility Education Innovative Strategies (PREIS) grantees. Data will be used to determine if PREP and PREIS grantees are meeting performance benchmarks related to the program's mission and priorities.

Respondents: Performance measurement data collection instruments will be administered to individuals representing SPREP, TPREP, CPREP, and PREIS grantees, their subawardees, and program participants.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Entry Survey	414,747	138,249	1	0.13333	18,433
Exit Survey	331,797	110,599	1	0.25	27,650
Core measures	16,000	5,333	3	0.08	1,280
Performance Measures Data Report Form (grantees).	279	93	2	18 for S/T; 14 for CPREP and PREIS.	3,076
Performance Measures Data Report Form (sub-awardees).	1,248	416	2	14 for S/T; 12 for CPREP	11,472
Estimated Total Annual Burden Hours.					61,911

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project. Email: *OIRA_SUBMISSION@OMB.EOP.GOV.* Attn: Desk Officer for the Administration for Children and Families.

Naomi Goldstein,

ACF/OPRE Certifying Officer.

[FR Doc. 2016–22316 Filed 9–15–16; 8:45 am]

BILLING CODE 4184–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2843]

Qualification of Biomarker—Total Kidney Volume in Studies for Treatment of Autosomal Dominant Polycystic Kidney Disease; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled "Qualification of Biomarker—Total Kidney Volume in Studies for Treatment of Autosomal Dominant Polycystic Kidney Disease." This guidance provides a qualified context of use (COU) for total kidney volume (TKV), measured at baseline, to be used as a prognostic enrichment biomarker to select patients with autosomal dominant polycystic kidney disease (ADPKD) at high risk for a "progressive decline" in renal function, defined as a confirmed 30 percent decline in the patient's estimated glomerular filtration rate (eGFR), for inclusion in interventional clinical trials. This guidance also describes the experimental conditions and constraints for which this biomarker is qualified through the Center for Drug Evaluation and Research (CDER) Biomarker Qualification Program. This biomarker can be used by drug developers for the qualified COU in submissions of investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs)without the relevant CDER review group reconsidering and reconfirming the suitability of the biomarker.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comment as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2015–D–2843 for "Qualification of Biomarker—Total Kidney Volume in Studies for Treatment of Autosomal Dominant Polycystic Kidney Disease; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Marianne Noone, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 4528, Silver Spring, MD 20993–0002, 301–796–2600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Qualification of Biomarker—Total Kidney Volume in Studies for Treatment of Autosomal Dominant Polycystic Kidney Disease." In the **Federal Register** of January 7, 2014 (79 FR 831), FDA announced the availability of a guidance for industry entitled "Qualification Process for Drug Development Tools" that described the process that would be used to qualify Drug Development Tools (DDTs) and to make new DDT qualification recommendations available on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* The qualification recommendations in the current guidance were developed using the process described in that 2014 guidance, and the current guidance is an attachment to that 2014 guidance.

In the **Federal Register** of August 17, 2015 (80 FR 49244), FDA announced the availability of a draft guidance entitled "Qualification of Biomarker—Total Kidney Volume in Studies for Treatment of Autosomal Dominant Polycystic Kidney Disease." The Agency did not receive any comments on that draft guidance during the public comment period. The current guidance finalizes that draft guidance.

This guidance provides recommendations for the use of TKV, measured at baseline, as a prognostic enrichment biomarker to select patients with ADPKD at high risk for a "progressive decline" in renal function, defined as a confirmed 30 percent decline in the patient's eGFR, for inclusion in interventional clinical trials. This biomarker may be used in combination with the patient's age and baseline eGFR as an enrichment factor in these interventional clinical trials. Specifically, this guidance provides the COU for which this biomarker is qualified through the CDER Biomarker Qualification Program. "Biomarker qualification" is a conclusion that within the stated COU, the biomarker can be relied upon to have a specific interpretation and application in drug development and regulatory review. This biomarker can be used by drug developers for the qualified COU in submission of INDs, NDAs, and BLAs without the relevant CDER review group reconsidering and reconfirming the suitability of the biomarker. After a biomarker is qualified for the specific COU, its qualification is not limited to a single, specific drug development program. Making the qualification recommendations widely known and available for use by drug developers will contribute to drug innovation, thus supporting public health.

Innovative and improved DDTs can help streamline the drug development process, improve the chances for clinical trial success, and yield more information about a treatment and/or disease. DDTs include, but are not limited to, biomarkers, clinical outcome assessments and animal models under the animal rule. Refer to DDTs Qualification Programs at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/default.htm* for additional information.

CDER has initiated this formal qualification process to work with developers of these biomarker DDTs to guide them as they refine and evaluate DDTs for use in the regulatory context. Once qualified, biomarker DDTs will be publicly available for use in any drug development program for the qualified COU. As described in the January 2014 guidance, biomarker DDTs should be developed and reviewed using this process.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the use of TKV, measured at baseline, as a prognostic enrichment biomarker to select patients with ADPKD at high risk for a "progressive decline" in renal function, defined as a confirmed 30 percent decline in the patient's eGFR, for inclusion in interventional clinical trials. This biomarker may be used in combination with the patient's age and baseline eGFR as an enrichment factor in these interventional clinical trials. This guidance does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance contains an information collection that is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The information collection has been approved under the OMB control numbers 0910–0001 and 0910–0014. The information requested in this guidance is currently submitted to FDA to support medical product effectiveness (see 21 CFR 312.30, 21 CFR 314.50(d)(5), and 21 CFR 314.126(b)(6)).

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/*

Guidances/default.htm or *http://www.regulations.gov.*

Dated: September 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22347 Filed 9–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3399]

Recommendations for Microbial Vectors Used for Gene Therapy; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled "Recommendations for Microbial Vectors Used for Gene Therapy; Guidance for Industry." The guidance document provides investigational new drug application (IND) sponsors, with recommendations concerning IND submissions for microbial vectors used for gene therapy (MVGTs) in early phase clinical trials. The guidance focuses on the chemistry, manufacturing, and control (CMC) information that sponsors should submit in an IND for MVGTs and provides an overview of preclinical and clinical considerations for these products. The guidance announced in this notice finalizes the draft guidance of the same title dated October 2015 and supplements the guidance entitled "Guidance for FDA Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs)," dated April 2008.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2015–D–3399 for "Recommendations for Microbial Vectors Used for Gene Therapy; Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Recommendations for Microbial Vectors Used for Gene Therapy; Guidance for Industry." The guidance provides IND sponsors, with recommendations concerning IND submissions for microbial vectors used for MVGTs in early phase clinical trials. The guidance focuses on the CMC information that sponsors should submit in an IND for MVGTs and provides an overview of preclinical and clinical considerations for these products.

In the **Federal Register** of October 14, 2015 (80 FR 61822), FDA announced the availability of the draft guidance of the same title dated October 2015. FDA received one comment on the draft guidance and that comment was considered as the guidance was finalized. Minor editorial changes were made in response to the comment to improve clarity. The guidance announced in this notice finalizes the draft guidance dated October 2015 and supplements the guidance entitled "Guidance for FDA Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs)," dated April 2008.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on recommendations for MVGTs. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 211 and 610 have been approved under OMB control number 0910–0139 and in 21 CFR part 312 under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: September 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22353 Filed 9–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1214]

Clinical Investigator Training Course

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation (M–CERSI), is announcing a 3-day training course for clinical investigators on the scientific, ethical, and regulatory aspects of clinical trials for medical products. This training course is intended to provide clinical investigators, such as clinicians, nurses, pharmacists, and other health care providers involved in conducting clinical trials, with expertise in the design, conduct, and analysis of clinical trials; to improve the quality of clinical trials; and to enhance the safety of trial participants. Senior FDA staff, along with other experts, will present on issues critical for successful conduct of clinical research.

DATES: The training course will be held on November 7, 2016, from 8:20 a.m. to 5:30 p.m. (registration begins at 7:30 a.m.); on November 8, 2016, from 8:30 a.m. to 4:45 p.m.; and on November 9, 2016, from 8:30 a.m. to 3:30 p.m.

ADDRESSES: The course will be held at the Silver Spring Civic Building at Veterans Plaza, One Veterans Place, Silver Spring, MD 20910. GPS device address: 8525 Fenton St., Silver Spring, MD 20910. For additional information, please refer to *http://www.silverspringdowntown.com/go/silver-spring-civic-building-and-veterans-plaza.* (FDA has verified the Web address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

FOR FURTHER INFORMATION CONTACT: Nicole Silva, Office of Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6323, Silver Spring, MD 20993, 301–796–3419, *Nicole.Silva@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Clinical trial investigators play a critical role in the development of medical products. They bear the responsibility for ensuring the safe and ethical treatment of study subjects and for acquiring adequate and reliable data to support regulatory decisions. This course is intended to train clinical investigators in all elements of clinical trials, including the preclinical and clinical information needed to support the investigational use of medical products; the statistical design of trials; and scientific, regulatory, and ethical considerations related to conduct of clinical trials. The course lecturers will include a diverse representation of senior FDA staff and other experts, enabling communication on issues critical for successful conduct of clinical research.

II. Description of the Training Course

A. Purpose

The training course is designed to provide clinical investigators with an overview of the following information:

- The essential toxicological, pharmacological, and manufacturing data to support investigational use in humans;
- Fundamental issues in the design and conduct of clinical trials;
- Statistical and analytic considerations in the interpretation of trial data;
- Appropriate safety evaluation during studies; and
- The ethical considerations and regulatory requirements for clinical trials.

In addition, the course aims to:

- Foster a cadre of clinical investigators with knowledge, experience, and commitment to investigational medicine;
- Promote communication between clinical investigators and FDA;
- Enhance investigators' understanding of FDA's role in experimental medicine;
- Improve the quality of clinical trial data; and
- Enhance protection of subjects in clinical trials.

B. Agenda

The course will be conducted over 3 days and will be presented mainly by senior FDA staff with other lecturers presenting on selected topics. The agenda is available at *http://www.fda.gov/Training/ClinicalInvestigator TrainingCourse/default.htm.*

C. Target Audience

The course is targeted toward clinicians, nurses, pharmacists and other health care professionals responsible for, or involved in, the conduct and/or design of clinical trials.

Registration: There is no registration fee to attend this in-person training course; however, seats are limited and registration will be on a first-come, first-served basis. To register, you need to complete the registration online by October 28, 2016, at *http://www.fda.gov/Training/ClinicalInvestigatorTrainingCourse/default.htm.* Upon completion of registration, you will receive an email that confirms your registration. There will be no onsite registration or remote access for this training.

Accommodations: Attendees are responsible for their own hotel accommodations. If you need special accommodations due to a disability, please contact Nicole Silva (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance. Persons attending the course are advised that FDA is not responsible for providing access to electrical outlets.

Dated: September 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22348 Filed 9–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1853]

Agency Information Collection Activities; Proposed Collection; Comment Request; Unique Device Identification System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with the Unique Device Identification System.

DATES: Submit either electronic or written comments on the collection of information by November 15, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–D–1853 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Unique Device Identification System." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Unique Device Identification System—21 CFR Parts 16, 801, 803, 806, 810, 814, 820, 821, 822 and 830—OMB Control Number 0910–0720—Extension

In accordance with the collection of information entitled "Unique Device Identification System (UDI)," medical device labelers, unless excepted, are required to design and use medical device labels and device packages that bear a UDI, present dates on labels in a particular format, and submit data concerning each version or model of a device to the Global Unique Device Identification Database (GUDID) no later than the date the label of the device must bear a UDI. Once a device becomes subject to UDI requirements, respondents will be required to update the information reported whenever the information changes.

The recordkeeping, reporting, and third-party disclosure requirements referenced in this document are imposed on any person who causes a label to be applied to a device, or who causes the label to be modified, with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label. In most instances, the labeler would be the device manufacturer, but other types of labelers include a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler. Respondents may also include any private organization that applies for accreditation by FDA as an issuing agency.

FDA has identified the following requirements as having burdens that must be accounted for under the PRA; the burdens associated with these requirements are summarized in the table that follows:

Section 801.18 requires that whenever a labeler of a medical device includes an expiration date, a date of manufacture, or any other date intended to be brought to the attention of the user of the device, the labeler must present the date on the label in a format that meets the requirements of this section.

Section 801.20 requires every medical device label and package to bear a UDI.

Under § 801.35, any labeler of a device that is not required to bear a UDI on its label may include a UDI on the label of that device and utilize the GUDID.

Under § 801.45, any device that has to be labeled with a UDI also has to bear a permanent marking providing the UDI on the device itself if the device is intended for more than one use and intended to be reprocessed before each use.

Section 801.50 requires stand-alone software to comply with specific labeling requirements that identify the software.

Section 801.55 authorizes additional, case-by-case, labeling exceptions and alternatives to standard UDI labeling requirements.

If a labeler relabels or modifies a label of a device that is required to bear a UDI, under § 830.60 it has to keep a record showing the relationship of the original device identifier to the new device identifier.

Section 830.110 requires an applicant seeking initial FDA accreditation as a UDI-issuing agency to furnish FDA an application containing certain information, materials, and supporting documentation.

Under § 830.120, an FDA-accredited issuing agency is required to disclose information concerning its system for the assignment of UDIs; maintain a list of labelers that use its system for the assignment of UDIs, and provide FDA a copy of such list; and upon request, provide FDA with information concerning a labeler that is employing the issuing agency's system for assignment of UDIs.

Sections 830.310 and 830.320 require the labeler to provide certain information to the GUDID concerning the labeler and each version or model of a device required to be labeled with a UDI, unless the labeler obtains a waiver.

Section 830.360 requires each labeler to retain records showing all UDIs used to identify devices that must be labeled with a UDI and the particular version or model associated with each device identifier, until 3 years after it ceases to market a version or model of a device.

Respondents who are required to submit data to the Agency under certain other approved information collections (listed below) are required to include UDI data elements for the device that is the subject of such information collection. Addition of the UDI data elements is included in this burden estimate for the conforming amendments in the following 21 CFR parts:

- Part 803—Medical Device Reporting (OMB control number 0910–0437)
- Part 806—Medical Devices; Reports of Corrections and Removals (OMB control number 0910–0359)
- Part 814—Premarket Approval of Medical Devices (OMB control number 0910–0231)
- Part 820—Quality System Regulation (OMB control number 0910–0073)
- Part 821—Medical Device Tracking Requirements (OMB control number 0910–0442)
- Part 822—Postmarket Surveillance (OMB control number 0910–0449)

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL BURDEN [1]

	Number of respondents [2]	Number of responses per respondent [3]	Total annual responses [4]	Average burden per response (in hours) [5]	Total hours [6]
Reporting	6,199	51	316,149	0.023 [1 minute]	7,271
Recordkeeping	5,987	51	305,337	0.989 [59 minutes]	301,978
Third-Party Disclosure	5,987	51	305,337	0.885 [53 minutes]	270,223

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] Maximum No. of Respondents for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer respondents.

[3] Maximum No. of Responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer responses.

[4] Maximum Total Annual Responses for any regulatory requirement within each category. Individual regulatory requirements within the category may involve fewer total annual responses.

[5] Rounded to three decimals. Total Hours reflects a more precise, non-rounded Average Burden per Response. An approximate (non-rounded) conversion to minutes is shown in square brackets.

[6] Total Hours is based on a more precise Burden per Response than the rounded value shown in this table.

Dated: September 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22340 Filed 9–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–E–2372]

Determination of Regulatory Review Period for Purposes of Patent Extension; LUMASON

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LUMASON and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by November 15, 2016. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 15, 2017. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2014–E–2372 for "Determination of Regulatory Review Period for Purposes of Patent Extension; LUMASON." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, LUMASON (sulfur hexafluoride microbubbles). LUMASON is an ultrasound contrast agent indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border. Subsequent to this approval, the USPTO received a patent term restoration application for LUMASON (U.S. Patent No. 5,686,060) from Bracco Suisse SA, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 22, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of LUMASON represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for LUMASON is 7,199 days. Of this time, 6,174 days occurred during the testing phase of the regulatory review period, while 1,025 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* January 26, 1995. The applicant claims December 23, 1994, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 26, 1995, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 21, 2011. The applicant claims December 20, 2011, as the date the NDA for LUMASON was initially submitted. However, FDA records indicate that NDA 203684 was submitted on December 21, 2011.

3. *The date the application was approved:* October 10, 2014. FDA has verified the applicant's claim that NDA 203684 was approved on October 10, 2014.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: September 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22345 Filed 9–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–E–2084]

Determination of Regulatory Review Period for Purposes of Patent Extension; RESQCPR SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for RESQCPR SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by November 15, 2016. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 15, 2017. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2015–E–2084 for "Determination of Regulatory Review Period for Purposes of Patent Extension; RESQCPR SYSTEM." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device RESQCPR SYSTEM. RESQCPR SYSTEM is indicated for use as a CPR adjunct to improve the likelihood of survival in adult patients with non-traumatic cardiac arrest. Subsequent to this approval, the USPTO received a patent term restoration application for RESQCPR SYSTEM (U.S. Patent No. 5,454,779) from University of California and Advanced Circulatory Systems, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 15, 2015, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of RESQCPR SYSTEM represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for RESQCPR SYSTEM is 3,608 days. Of this time, 2,247 days occurred during the testing phase of the regulatory review period, while 1,361 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* April 21, 2005. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective on October 3, 2005. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on April 21, 2005, which represents the IDE effective date.
2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* June 15, 2011. FDA has verified the applicant's claim that the premarket approval application (PMA) for RESQCPR SYSTEM (PMA P110024) was initially submitted June 15, 2011.
3. *The date the application was approved:* March 6, 2015. FDA has verified the applicant's claim that PMA P110024 was approved on March 6, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: September 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22343 Filed 9–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–E–2354]

Determination of Regulatory Review Period for Purposes of Patent Extension; ENTYVIO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ENTYVIO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patents and Trademarks Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by November 15, 2016. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 15, 2017. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions)*: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2014–E–2354.

For Determination of Regulatory Review Period for Purposes of Patent Extension: ENTYVIO. Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product, ENTYVIO (vedolizumab). ENTYVIO is indicated for adult ulcerative colitis and adult Crohn's disease. Subsequent to this approval, the USPTO received a patent term restoration application for ENTYVIO (U.S. Patent No. 7,147,851) from Millenium Pharmaceuticals, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 6, 2016, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of ENTYVIO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ENTYVIO is 5,066 days. Of this time, 4,731 days occurred during the testing phase of the regulatory review period, while 335 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* July 8, 2000. The applicant claims August 18, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 8, 2000, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* June 20, 2013. FDA has verified the applicant's claim that the biologics license application (BLA) for ENTYVIO (BLA 125476) was initially submitted on June 20, 2013.

3. *The date the application was approved:* May 20, 2014. FDA has verified the applicant's claim that BLA 125476 was approved on May 20, 2014.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,526 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Dated: September 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22344 Filed 9–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public workshop regarding "Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices (ASTs)." This public workshop is intended to facilitate discussion between drug sponsors and device manufacturers who are planning to develop new antimicrobial drugs or ASTs and who wish to coordinate development of these products, such that the AST device could be cleared either at the time of new drug approval or shortly thereafter. The input from this public workshop will also help in developing topics for future discussion.

DATES: *Dates and Times:* The public workshop will be held on September 29, 2016, from 9 a.m. to 4 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration information.

ADDRESSES: *Location:* The public workshop will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910. The hotel's phone number is 301–589–0800.

FOR FURTHER INFORMATION CONTACT: *Contact Persons:* Lori Benner and/or Jessica Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6221, Silver Spring, MD 20993–0002, 301–796–1300.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early. Seating will be available on a first-come, first-served basis. To register electronically, email your registration information (including name, title, firm name, address, telephone number, and fax number) to *AntimicrobialSusceptibilitytestingWorkshop2016@fda.hhs.gov.* Persons without access to the Internet can call 301–796–1300 to register.

If you need special accommodations due to a disability, please contact Jessica Barnes or Lori Benner (see *Contact Persons* above) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop pertaining to the coordinated development of antimicrobial drugs and ASTs. Discussions will focus on assisting drug sponsors and device manufacturers who are planning to develop new antimicrobial drugs or ASTs and who seek to coordinate development of these products.

The goals of the workshop are to: (1) Outline the regulatory considerations for submitting separate applications to the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health for antimicrobial drugs and ASTs, respectively; (2) identify the challenges related to obtaining data supporting the clearance of an AST device coincident with or soon after antimicrobial drug approval; and (3) discuss ideas for addressing these challenges.

The Agency encourages individuals, industry, device manufacturers, health care professionals, researchers, public health organizations and other interested persons to attend this public workshop. Workshop updates will be made available on the internet at *http://www.fda.gov/Drugs/NewsEvents/ucm512519.htm.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available either in hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.* Transcripts will also be available on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm512519.htm* approximately 45 days after the workshop.

Dated: September 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22352 Filed 9–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0045]

Waivers From the Requirement To Demonstrate Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles; Draft Revised Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft revised guidance for industry (GFI) #171 entitled "Waivers from the Requirement to Demonstrate Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles." This draft revised guidance document describes how the Center for Veterinary Medicine (CVM) intends to evaluate requests for waiving the requirement for submitting data demonstrating the bioequivalence of animal drugs in soluble powder oral dosage form products and Type A medicated articles. It expands upon CVM's Bioequivalence Guidance,[1] particularly the section on Criteria for Waiver of In Vivo Bioequivalence Study. This guidance is applicable to generic investigational new animal drug (JINAD) files and abbreviated new animal drug applications (ANADAs). Although the recommendations in this guidance reference generic drug applications, the general principles described may also be applicable to new animal drug applications (NADAs), investigational new animal drug (INAD) files, and supplemental NADAs.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft revised guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft revised guidance by November 15, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2004–D–0045 for "Waivers from the Requirement to Demonstrate Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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[1] CVM Guidance for Industry #35, "Bioequivalence Guidance," November 8, 2006 (see page 7): *http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052363.pdf.*

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft revised guidance document.

FOR FURTHER INFORMATION CONTACT: Charli Long, Center for Veterinary Medicine (HFV–170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0850, *charli.long-medrano@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft revised guidance for industry #171 entitled "Waivers from the Requirement to Demonstrate Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles." This draft revised guidance document describes how the Center for Veterinary Medicine (CVM) intends to evaluate requests for waiving the requirement for submitting data demonstrating the bioequivalence of animal drugs in soluble powder oral dosage form products and Type A medicated articles. It expands upon CVM's Bioequivalence Guidance,[2] particularly the section on Criteria for Waiver of In Vivo Bioequivalence Study. This draft revised guidance document is intended to provide clarification of the scientific basis for concepts and recommendations conveyed in the original guidance. In addition, the table containing estimated gastric volumes for each of the various animal species has been revised. However, applicants may propose an alternative gastric volume value for a particular species when using the dosage adjusted approach. No new concepts have been introduced in this draft revised guidance and its scope has not been modified.

II. Significance of Guidance

This level 1 draft revised guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft revised guidance, when finalized, will represent the current thinking of FDA on "Waivers from the Requirement to Demonstrate Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft revised guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information referred to in the guidance entitled "Waivers from the Requirement to Demonstrate Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles" have been approved under OMB control number 0910–0575.

IV. Electronic Access

Persons with access to the Internet may obtain the draft revised guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: September 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22339 Filed 9–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Menu Labeling Public Workshop; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing a third public meeting to discuss menu labeling requirements. We announced the first two public meetings in a separate **Federal Register** notice earlier this year. The purpose of the public meetings is to help the regulated industry comply with the requirements of the menu labeling final rule.

DATES: See "How to Participate in the Public Meeting" in the **SUPPLEMENTARY INFORMATION** section of this document for dates, times, and addresses of the public meeting, closing date for advance registration, requesting special accommodations due to disability, and other information.

ADDRESSES: See "How to Participate in the Public Meeting" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For questions about registering for this meeting or for special accommodations due to disability, contact Cindy de Sales, The Event Planning Group, 8720 Georgia Ave., Suite 801, Silver Spring, MD 20910, 240–316–3207, FAX: 240–652–6002, email: *rsvp@tepgevents.com.*

For general questions about the public meeting, contact Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 1, 2014 (79 FR 71156), we published a final rule on nutrition labeling of standard menu items in restaurants and similar retail food establishments; the rule is codified at Title 21 of the *Code of Federal Regulations,* section 101.11. The final rule implements section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(q)(5)(H)), which, in general, requires that restaurants and similar retail food establishments that are part of a chain with 20 or more locations, doing business under the same name, and offering for sale substantially the same menu items, provide calorie information for standard menu items (including food on display and self-service food); provide, upon request, additional written nutrition information for standard menu items; and comply with other requirements described in section 403(q)(5)(H) of the FD&C Act.

On December 18, 2015, the President signed the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Section 747 of the Consolidated Appropriations Act states that none of the funds made available under the Consolidated Appropriations Act may be used to implement, administer, or enforce the final rule entitled "Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments" until 1 year after the date of publication of a Level 1 guidance with respect to nutrition labeling of standard menu items in restaurants and similar retail food establishments.

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[2] CVM Guidance for Industry #35, "Bioequivalence Guidance," November 8, 2006 (see page 7): *http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052363.pdf.*

In the **Federal Register** of May 5, 2016 (81 FR 27067), we announced the availability of the guidance for industry entitled "A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Foods—Part II (Menu Labeling Requirements in Accordance with 21 CFR 101.11)." The guidance uses a question and answer format and is intended to help restaurants and similar retail food establishments covered by the final rule comply with the nutrition labeling requirements of the final rule. In accordance with the Consolidated Appropriations Act, 2016, enforcement of the final rule will commence May 5, 2017.

We have made education of the menu labeling requirements a high priority, and this is our third menu labeling workshop to educate interested members of the public, especially the regulated industry, about the menu labeling requirements. We announced the first two public meetings in a separate **Federal Register** notice on June 15, 2016 (81 FR 39056). Interested persons can continue to submit general questions to *CalorieLabeling@fda.hhs.gov*.

II. Purpose and Format of the Public Meeting

The purpose of this public meeting is to help the regulated industry comply with the requirements of the menu labeling final rule. On the morning of day one of the meeting, we will give a slide presentation on the menu labeling requirements. (Please note the slide presentation will only be presented on day one.) The afternoon of day one and all of day two will consist of consultation sessions with FDA staff where individual companies (limited to two members per company) may discuss their specific questions and concerns. Each consultation session is limited to 15 minutes to help ensure that enough time is available to accommodate each company that requests a consultation. We recommend that participants in the consultation session prepare their questions in advance due to the limited time available.

III. How To Participate in the Public Meeting

We encourage all persons who wish to attend the meeting to register in advance of the meeting and to indicate whether they are requesting a consultation session. There is no fee to register for the public meeting, and registration will be on a first-come, first-served basis. Early registration is recommended to facilitate planning of the consultation sessions and because seating is limited. We encourage you to use electronic registration if possible (see the address in table 1).

Table 1 provides information on participation in the public meeting.

TABLE 1—INFORMATION ON MENU LABELING MEETING

Activity	Date	Electronic address	Address
Public meeting	November 16 and 17, 2016, 8 a.m. to 4:30 p.m.		Holiday Inn Hotel & Suites Oakland Airport, 77 Hegenberger Rd., Oakland, CA 94621.
Advance registration	by November 9, 2016	*http://www.cvent.com/d/zfq6sm*	We encourage you to use electronic registration if possible.[1]
Request special accommodations due to a disability.	by November 9, 2016		See **FOR FURTHER INFORMATION CONTACT**.

[1] You may also register via mail, fax, or email. Please include your name, title, firm name, address, and phone and fax numbers in your registration information and send to: Cindy de Sales, The Event Planning Group, 8720 Georgia Ave., Suite 801, Silver Spring, MD 20910, 240–316–3207, FAX: 240–652–6002, email: *rsvp@tepgevents.com*.

IV. Transcripts

Transcripts of the workshop will not be prepared.

Dated: September 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22337 Filed 9–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a virtual meeting of the Frederick National Laboratory Advisory Committee to the National Cancer Institute.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting will also be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (*http://videocast.nih.gov/*).

Name of Committee: Frederick National Laboratory Advisory Committee to the National Cancer Institute.

Date: October 21, 2016.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: Report from the FNLAC RAS Workgroup.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room TE406, Rockville, MD 20850, (Virtual Meeting).

Contact Person: Peter L. Wirth, Ph.D., Executive Secretary, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 9609 Medical Center Drive, Room 7W514, Bethesda, MD 20892, 240–276–6434, *wirthp@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NCI Shady Grove has instituted stringent procedures for entrance into the NCI Shady Grove building. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/fac/fac.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 12, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–22274 Filed 9–15–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of a meeting of the NIH Clinical Center Research Hospital Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The portions of the meeting devoted to the identification and evaluation of specific candidates for consideration for leadership positions in the Clinical Center will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B) and 552b(c)(6), title 5 U.S.C., as amended. Premature disclosure of potential candidates and their qualifications, as well as the discussions by the committee, could significantly frustrate NIH's ability to recruit these individuals and the consideration of personnel qualifications, performance, and the competence of individuals as candidates would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIH Clinical Center Research Hospital Board.

Date: October 21, 2016.

Open: 9:00 a.m. to 3:00 p.m.

Agenda: Welcome and NIH Director's Overview, Clinical Center Patient and Worker Safety Metrics, Clinical Center Outreach and Engagement, and Update on Aseptic Preparation Facilities.

Place: Conference Room 6C6, Building 31, National Institutes of Health, Bethesda, MD 20892.

Closed: 3:15 p.m. to 5:00 p.m.

Agenda: Identification of Candidates for Leadership Roles.

Place: Conference Room 6C6, Building 31, National Institutes of Health, Bethesda, MD 20892.

Contact Person: Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, 301–496–4272, *woodgs@od.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Dated: September 12, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–22273 Filed 9–15–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NIDCD.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute on Deafness and Other Communication Disorders, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIDCD.

Date: October 24, 2016.

Open: 8:00 a.m. to 8:15 a.m.

Agenda: Reports from the institute staff.

Place: National Institutes of Health; Porter Neuroscience Research Center, Room 610, Building 35A Convent Drive, Bethesda, MD 20892.

Closed: 8:20 a.m. to 5:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health; Porter Neuroscience Research Center, Room 610, Building 35A Convent Drive, Bethesda, MD 20892.

Contact Person: Andrew J. Griffith, MD, Ph.D., Director, Division of Intramural Research, National Institute on Deafness and Other Communication Disorders, 35A Convent Drive, GF 103, Rockville, MD 20892, 301–496–1960, *griffita@nidcd.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.nidcd.nih.gov/about/groups/bsc/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: September 12, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–22271 Filed 9–15–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; U01 Review.

Date: October 11, 2016.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health, Rockville, MD 20850, 301–402–3587, *rayk@nidcd.nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; NIDCD Translating Basic Hearing and Balance Research into Clinical Tools.

Date: October 12, 2016.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Katherine Shim, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIH/NIDCD, 6001 Executive Blvd., Room 8351, Bethesda, MD 20892, 301–496–8683, *katherine.shim@nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Chemosensory Fellowship Review.

Date: October 13, 2016.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Shiguang Yang, DVM, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIDCD, NIH, 6001 Executive Blvd., Room 8349, Bethesda, MD 20892, 301–496–8683, *yangshi@nidcd.nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Hearing and Balance Fellowships Review.

Date: October 18, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Sheo Singh, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, 6001 Executive Blvd., Room 8351, Bethesda, MD 20892, 301–496–8683, *singhs@nidcd.nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Translational Grant Review.

Date: October 19, 2016.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Sheo Singh, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, 6001 Executive Blvd., Room 8351, Bethesda, MD 20892, 301–496–8683, *singhs@nidcd.nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; VSL Fellowships Review.

Date: October 24, 2016.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Katherine Shim, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIH/NIDCD, 6001 Executive Blvd., Room 8351, Bethesda, MD 20892, 301–496–8683, *katherine.shim@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: September 12, 2016.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–22272 Filed 9–15–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Proteogenomic Translational Research Centers.

Date: October 25, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jeffrey E. DeClue, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, 7W238, Bethesda, MD 20892–9750, 240–276–6371, *decluej@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Physical Sciences-Oncology Projects (U01).

Date: October 27, 2016.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7E032/034, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Scott A. Chen, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, 7W604, Rockville, MD 20850, 240–276–6038, *chensc@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Provocative Question #5.

Date: November 2, 2016.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Shady Grove, 9609 Medical Center Drive, Room 7W104, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Eun Ah Cho, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, 7W104, Bethesda, MD 20892–9750, 240–276–6342, *choe@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Provocative Question #12

Date: November 8, 2016.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W030, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Jennifer C. Schiltz, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, 7W634, Rockville, MD 20850, 240–276–5864, *jennifer.schiltz@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and

Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 12, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–22275 Filed 9–15–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

CARA Act's Required Training of Nurse Practitioners and Physician Assistants

AGENCY: Substance Abuse and Mental Health Services Administration, United States Department of Health and Human Services (HHS).

ACTION: Notice of public meeting.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA) announces that it will hold a public meeting on October 1, 2016, to discuss the training requirements for nurse practitioners (NPs) and physician assistants (PAs) that have been stipulated in the Comprehensive Addiction and Recovery Act (CARA). The session will be held in Newark, NJ.

DATES: The meeting will be held on October 1, 2016, from 9:00 to 11:00 a.m.

ADDRESSES:

In Person: The meeting will be held at the Newark Liberty International Airport Marriott, 1 Hotel Rd, Newark, NJ 07114.

By Phone: Phone Number: 888–942–9687, Passcode: 5093420.

By Internet: URL: *https://www.mymeetings.com/emeet/rsvp/index.jsp?customHeader=mymeetings&Conference_ID=1063134&passcode=5093420,* Conference number: 1063134, Passcode: 5093420.

SAMHSA will post additional logistical information on how to participate in person, by phone, or on the Web at: *http://caralisteningsession.eventbrite.com* in advance of the listening session.

FOR FURTHER INFORMATION CONTACT: For additional information concerning the meeting, please contact: Dr. Mitra Ahadpour, Director, Division of Pharmacological Therapies, Center for Substance Abuse Treatment, SAMHSA, (240) 276–2134 or *mitra.ahadpour@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

On July 22, 2016 CARA was signed into law by President Obama. The new law authorizes dispensing privileges of covered medications in office-based settings by NPs and PAs for five years (until October 1, 2021). At this meeting, SAMHSA will be seeking input on how to best implement the requirements that all NPs and PAs must have twenty-four hours of training before obtaining a waiver to prescribe covered medications. The meeting will include the organizations listed in statute and is also open to the public. Specifically, SAMHSA is seeking input on existing training programs that may meet the statutory requirements for training and within the twenty-four hours of training, the number of hours that NPs and PAs should complete on each topic listed in the CARA Act (Pub. L. 114–198).

The agenda will include:

—Welcome and introductions
—Review of CARA Training Requirements
—Discussion about Training Requirements

Carlos Castillo,

Committee Management Officer.

[FR Doc. 2016–22279 Filed 9–15–16; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Saybolt LP as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Saybolt LP as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Saybolt LP has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of June 14, 2016.

DATES: The accreditation and approval of Saybolt LP as commercial gauger and laboratory became effective on June 14, 2016. The next triennial inspection date will be scheduled for June 2019.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Saybolt LP, 2610 Federal Highway, Ft. Lauderdale, FL 33316, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Saybolt LP is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
9	Density Determinations.
12	Calculations.

Saybolt LP is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–08	D86	Standard Test Method for Distillation of Petroleum Products.
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–53	D2709	Standard Test Method for Water and Sediment in Middle Distillate Fuels by Centrifuge.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: September 12, 2016.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2016–22311 Filed 9–15–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0082]

Agency Information Collection Activities: African Growth and Opportunity Act Certificate of Origin

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; Extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: African Growth and Opportunity Act Certificate of Origin (AGOA). CBP is proposing that this information collection be extended with a change to the burden hours. There is no change to the information collected. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before October 17, 2016 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Paperwork Reduction Act Officer, U.S. Customs and Border Protection, Regulations and Rulings, Office of Trade, 90 K Street, NE., 10th Floor, Washington, DC 20229–1177, or via email (*CBP_PRA@cbp.dhs.gov*). Please note contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs please contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP Web site at *https://www.cbp.gov/.* For additional help: *https://help.cbp.gov/app/home/search/1.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** (81 FR 28096) on May 9, 2016, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10. CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden, including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: African Growth and Opportunity Act Certificate of Origin.

OMB Number: 1651–0082.

Form Number: None.

Abstract: The African Growth and Opportunity Act (AGOA) was adopted by the United States with the enactment of the Trade and Development Act of 2000 (PL.106–200). The objectives of AGOA are (1) to provide for extension of duty-free treatment under the Generalized System of Preferences (GSP) to import sensitive articles normally excluded from GSP duty treatment, and (2) to provide for the entry of specific textile and apparel articles free of duty and free of any quantitative limits from the countries of sub-Saharan Africa.

For preferential treatment under AGOA, the exporter is required to prepare a certificate of origin and provide it to the importer. The certificate of origin includes information such as contact information for the importer, exporter and producer; the basis for which preferential treatment is claimed; and a description of the imported merchandise. The importers are required to have the certificate in their possession at the time of the claim, and to provide it to Customs and Border Protection (CBP) upon request. The collection of this information is provided for in 19 CFR 10.214, 10.215, and 10.216.

Instructions for complying with this regulation are posted on CBP.gov Web site at: *http://www.cbp.gov/trade/priority-issues.*

Action: CBP proposes to extend the expiration date of this information collection without change to the estimated burden hours or the information collected.

Type of Review: Extension (with change to burden hours).

Affected Public: Businesses.

Estimated Number of Respondents: 12.

Estimated Number of Annual Responses per Respondent: 2.

Estimated Number of Total Annual Responses: 24.

Estimated Time per Response: 20 minutes.

Estimated Total Annual Burden Hours: 8.16.

Dated: September 13, 2016.

Seth Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2016–22364 Filed 9–15–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Amspec Services, LLC, as a Commercial Gauger And Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of AmSpec Services, LLC, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that AmSpec Services, LLC, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of February 17, 2016.

DATES: The accreditation and approval of AmSpec Services, LLC, as commercial gauger and laboratory became effective on February 17, 2016. The next triennial inspection date will be scheduled for February 2019.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that AmSpec Services, LLC, 1203 East Highway 30, Gonzales, LA 70737, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. AmSpec Services, LLC is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
11	Physical Properties.
12	Calculations.
17	Maritime Measurement.

AmSpec Services, LLC is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	D287	Standard Test Method for API Gravity of crude Petroleum and Petroleum Products.
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27–05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids.
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–54	D1796	Standard Test Method for Water and Sediment in Fuel Oils by the Centrifuge Method.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: September 12, 2016.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2016–22303 Filed 9–15–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Saybolt LP as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Saybolt LP as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Saybolt LP has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of March 16, 2016.

DATES: The accreditation and approval of Saybolt LP as commercial gauger and laboratory became effective on March 16, 2016. The next triennial inspection date will be scheduled for March 2019.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Saybolt LP, 1123 Highway 43, Saraland, AL 36571, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Saybolt LP is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
11	Physical Properties.

Saybolt LP is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	D287	Standard Test Method for API Gravity of crude Petroleum and Petroleum Products.
27–02	D1298	Standard Test Method for Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method.
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–08	D86	Standard Test Method for Distillation of Petroleum Products.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids.
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27–50	D93	Standard Test Methods for Flash-Point by Pensky-Martens Closed Cup Tester.
27–58	D5191	Standard Test Method For Vapor Pressure of Petroleum Products.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: September 12, 2016.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2016–22322 Filed 9–15–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of AmSpec Services, LLC, as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of AmSpec Services, LLC, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that AmSpec Services, LLC, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of April 6, 2016.

DATES: The accreditation and approval of AmSpec Services, LLC, as commercial gauger and laboratory became effective on April 6, 2016. The next triennial inspection date will be scheduled for April 2019.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that AmSpec Services, LLC, 2310 Hwy 69N, Nederland, TX 77627, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. AmSpec Services, LLC is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
12	Calculations.
17	Maritime Measurement.

AmSpec Services, LLC is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	D287	Standard Test Method for API Gravity of crude Petroleum and Petroleum Products.
27–05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov.* Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: September 12, 2016.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2016–22304 Filed 9–15–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Immigration and Customs Enforcement

[Docket No. ICEB–2016–0001]

Advisory Committee on Family Residential Centers

AGENCY: Immigration and Customs Enforcement, DHS.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The U.S. Immigration and Customs Enforcement (ICE) Advisory Committee on Family Residential Centers (ACFRC) will meet in Washington, DC to discuss ACFRC subcommittee reports and vote on potential recommendations. This meeting will be open to the public. Due to limited seating, individuals who wish to attend the meeting in person are required to register online at *www.ice.gov/acfrc.*

DATES: The ICE Advisory Committee on Family Residential Centers will meet on Friday, October 7, 2016, from 9:00 a.m. to 5:00 p.m. Please note that these meetings may conclude early if the Committee has completed all business.

ADDRESSES: The meeting will be held in the Julie Myers Conference Center at ICE Headquarters, 500 12th St. SW., Washington, DC 20536.

For information on facilities, services for individuals with disabilities, or to request special assistance at the meeting, contact Mr. John Amaya, Designated Federal Officer, at *ICE_ACFRC@ice.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. John Amaya, Designated Federal Officer for the Advisory Committee on Family Residential Centers, at *ICE_ACFRC@ice.dhs.gov.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the *Federal Advisory Committee Act* (FACA) (Title 5, United States Code (U.S.C.), Appendix). Under the Secretary of DHS's authority in Title 6, U.S.C., Section 451, this Committee is established in accordance with and operates under the provisions of the FACA. The Committee provides advice and recommendations to the Secretary of DHS through the Assistant Secretary of ICE on matters concerning ICE's family residential centers related to education, language services, detention management, medical treatment, and access to counsel.

Written statements may be submitted to the ACFRC Designated Federal Officer (DFO) (see **FOR FURTHER INFORMATION CONTACT**). Statements should be no longer than two typewritten pages and address the following details: The issue, discussion, and recommended course of action. Additional information, including the agenda and electronic registration details, is available on the ACFRC Web site at *www.ice.gov/acfrc.*

Meeting Agenda

The agenda for the Advisory Committee on Family Residential Centers meeting is as follows:

Friday, October 7, 2016

(1) Welcome and Opening Remarks
(2) Discussion of Subcommittee on Medical and Mental Health Report
(3) Public Comment
(4) Discussion of Subcommittee on Education
(5) Public Comment
(6) Lunch
(7) Discussion of Subcommittee on Access to Counsel and Language Access Report
(8) Public Comment
(9) Committee Votes on Potential Recommendations
(10) Closing Remarks
(11) Adjourn

The meeting agenda, Committee tasking, and all meeting documentation will be made available online at: *www.ice.gov/acfrc.* Alternatively, you may contact Mr. John Amaya as noted in the **FOR FURTHER INFORMATION CONTACT** section above.

During public oral comment periods, speakers are requested to limit their comments to 2 minutes. Please note that the public comment period may end before the time indicated, following the last call for comments.

Dated: September 13, 2016.

Molly Stubbs,

Supervisory Regulations Specialist, U.S. Immigration and Customs Enforcement.

[FR Doc. 2016–22326 Filed 9–15–16; 8:45 am]

BILLING CODE 9110–28–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5913–N–25]

60-Day Notice of Proposed Information Collection: Final Endorsement of Credit Instrument

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* November 15, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Daniel J. Sullivan, Acting Director, Office of Multifamily Productions, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email *Daniel.J.Sullivan@hud.gov* or telephone 202–402–6130. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Collette Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Final Endorsement of Credit Instrument.

OMB Approval Number: 2502–0016.

Type of Request: Extension of currently approved collection.

Form Number: HUD–92023.

Description of the need for the information and proposed use: The information collected on the Final Endorsement of Credit Instrument form is used to request final endorsement by HUD of the credit instrument. The mortgage/lender submits information to indicate the schedule of advances made on the project and the final advances to be disbursed immediately upon final endorsement.

Respondents (i.e. affected public): Business or other for-profit, Not-for-profit institutions, contractors, mortgagors/borrowers, and mortgagees/lenders.

Estimated Number of Respondents: 1,472.

Frequency of Response: 1.

Average Hours per Response: 1.

Total Estimated Burden: 1,472.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: August 31, 2016.

Genger Charles,

Senior Policy Advisor for Housing.

[FR Doc. 2016–22369 Filed 9–15–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5913–N–24]

60-Day Notice of Proposed Information Collection: Multifamily Project Construction Change

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* November 15, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Daniel J. Sullivan, Acting Director, Office Multifamily Productions, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email *Daniel.J.Sullivan@hud.gov* or telephone 202–402–6130. (This is not a toll-free number) Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Collette Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Multifamily Request for Construction Change.

OMB Approval Number: 2502–0011.

Type of Request: Extension of currently approved collection.

Form Number: HUD–92437, HUD–92441, HUD–92442, HUD–92442–A, HUD–92442–CA, HUD–92442–A–CA.

Description of the need for the information and proposed use: The information collected on the Multifamily Request for Construction Change form provides HUD with information from contractors, mortgagors/borrowers, and mortgagees/lenders for construction of multifamily projects and to obtain approval of changes in previously approved contract drawings and/or specifications.

Respondents (i.e. affected public): Business or other for-profit, Not-for-profit institutions, contractors, mortgagors/borrowers, and mortgagees/lenders.

Estimated Number of Respondents: 854.

Estimated Number of Responses: 854.

Frequency of Response: 1.

Average Hours per Response: 3.

Total Estimated Burden: 2,562.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: August 31, 2016.

Genger Charles,

Senior Policy Advisor for Housing.

[FR Doc. 2016–22370 Filed 9–15–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5907–N–38]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), call the toll-free Title V information line at 800–927–7588 or send an email to *title5@hud.gov* .

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to: Ms. Theresa M. Ritta, Chief Real Property Branch, the Department of Health and Human Services, Room 12–07, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–2265 (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 or send an email to *title5@hud.gov* for detailed instructions, or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*e.g.*, acreage, floor plan, condition of property, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: AGRICULTURE: Ms. Debra Kerr, Department of Agriculture, OPPM, Property Management Division, Agriculture South Building, 300 7th Street SW., Washington, DC 20024, (202) 720–8873; AIR FORCE: Mr. Robert E. Moriarty, P.E., AFCEC/CI, 2261 Hughes Avenue, Ste. 155, JBSA Lackland TX 78236–9853, (315) 225–7384; COE: Ms. Brenda Johnson-Turner, HQUSACE/CEMP–CR, 441 G Street NW., Washington, DC 20314, (202) 761–7238; NAVY: Ms. Nikki Hunt, Department of the Navy, Asset Management Division, Naval Facilities Engineering Command, Washington Navy Yard, 1330 Patterson Ave. SW., Suite 1000, Washington, DC 20374; (202) 685–9426; (These are not toll-free numbers).

Dated: September 12, 2016.

Brian P. Fitzmaurice,

Director, Division of Community Assistance, Office of Special Needs Assistance Programs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 09/16/2016

Suitable/Available Properties

Building

Kentucky

Buckhorn Lake Project, KY
804 Buckhorn Dam Road
Buckhorn KY 41721
Landholding Agency: COE
Property Number: 31201630020
Status: Excess
Directions: BUCKLK–32543, Structure 01C02 Bathhouse Facilities
Comments: Off-site removal only; 25+ yrs. old; 500 sq. ft.; toilets; contaminated with human waste; remediation required; contact COE for more information.

New Jersey

2 Buildings
New Jersey Ave.
Joint Base MDL NJ 08640
Landholding Agency: Air Force
Property Number: 18201630008
Status: Unutilized
Directions: 5882 (120 sq. ft.) & 5884 (196 sq. ft.)
Comments: Off-site removal only; 50+ yrs. old; sq. ft. listed above; storage; poor condition; contact AF for more information.

North Carolina

Radio Building (13209)
1070 Massey Branch Road
Robbinsville NC 28771
Landholding Agency: Agriculture
Property Number: 15201630019
Status: Excess
Comments: 34+ yrs. old; 53 sq. ft.; repeater/microwave building; roof needs replacing; contact USDA for more information.

Land

Illinois

Outer Marker & Bldg. 262
South East of Mascoutah off Highbanks Road
Mascoutah IL 62258

Landholding Agency: Air Force
Property Number: 18201630013
Status: Unutilized
Comments: 62+ yrs. old; 333 sq. ft.; unusable, beyond repair; asbestos walls; sits on .87 acres of land; requires easement for roads to access property; contact AF for more information.

Unsuitable Properties

Building

Colorado

Building 1606,
Fire Crash House; 560 S. Silver Creek Street
Buckley AFB CO 80011
Landholding Agency: Air Force
Property Number: 18201630012
Status: Unutilized
Comments: Public access denied and no alternative method to gain access without compromising national security; property located within an airport runway clear zone or military airfield.
Reasons: Within airport runway clear zone; Secured Area

Hawaii

Former MCCS Exchange Space/
Bldg. 4, MCBH, Camp Smith
Marine Corps Base Hawaii
Camp Smith HI 96861
Landholding Agency: Navy
Property Number: 77201630024
Status: Excess
Comments: Public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

Illinois

Building 434
434 Hangar Road
Scott AFB IL 62225
Landholding Agency: Air Force
Property Number: 18201630015
Status: Unutilized
Comments: Public access denied and no alternative method to gain access without compromising national security; property located within an airport runway clear zone or military airfield.
Reasons: Within airport runway clear zone; Secured Area

Kentucky

Rough River Lake Project, KY
14957 Falls of Rough/
Cave Creek Recreation Area
Rough River Lake KY
Landholding Agency: COE
Property Number: 31201630018
Status: Excess
Directions: Located within floodway which has not been corrected or contained
Comments: Documented deficiencies: cinder block waste holding tanks significantly deteriorated which is causing massive leaking and cannot be replaced; clear threat to physical safety.
Reasons: Floodway; Extensive deterioration

New Mexico

2 Buildings
208 W. Octagon Street
Cannon AFB NM 88103
Landholding Agency: Air Force
Property Number: 18201630010
Status: Underutilized
Directions: Transient Lodging 1818 & 1819
Comments: Public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

Range Support Building 3121
5000 Sundale Valley Road
Cannon AFB NM 88103
Landholding Agency: Air Force
Property Number: 18201630014
Status: Underutilized
Comments: Public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

Virginia

Building 101C, Lafayette
River Annex
6405 Hampton Blvd.
Norfolk VA 23551
Landholding Agency: Navy
Property Number: 77201630025
Status: Excess
Comments: Public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

Wyoming

3 Buildings
FE Warren AFB WY
FE Warren AFB WY WY 82005
Landholding Agency: Air Force
Property Number: 18201630009
Status: Unutilized
Directions: GHZG S–1, GHXX P–1, GHZT T–1
Comments: Public access denied and no alternative method to gain access without compromising national security.
Reasons: Secured Area

[FR Doc. 2016–22359 Filed 9–15–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2016–0120; FXIA16710900000–156–FF09A30000]

Endangered Species; Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species. With some exceptions, the Endangered Species Act (ESA) prohibits activities with listed species unless Federal authorization is acquired that allows such activities.

DATES: We must receive comments or requests for documents on or before October 17, 2016.

ADDRESSES:

Submitting Comments: You may submit comments by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–HQ–IA–2016–0120.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2016–0120; U.S. Fish and Wildlife Service Headquarters, MS: BPHC; 5275 Leesburg Pike, Falls Church, VA 22041–3803.

When submitting comments, please indicate the name of the applicant and the PRT# you are commenting on. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

Viewing Comments: Comments and materials we receive will be available for public inspection on *http://www.regulations.gov,* or by appointment, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays, at the U.S. Fish and Wildlife Service, Division of Management Authority, 5275 Leesburg Pike, Falls Church, VA 22041–3803; telephone 703–358–2095.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, 703–358–2104 (telephone); 703–358–2281 (fax); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I request copies of applications or comment on submitted applications?

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES**. If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

B. May I review comments submitted by others?

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), along with Executive Order 13576, "Delivering an Efficient, Effective, and Accountable Government," and the President's Memorandum for the Heads of Executive Departments and Agencies of January 21, 2009—Transparency and Open Government (74 FR 4685; January 26, 2009), which call on all Federal agencies to promote openness and transparency in Government by disclosing information to the public, we invite public comment on these permit applications before final action is taken.

III. Permit Applications

Endangered Species

Applicant: University of South Carolina, Columbia, SC; PRT–93065B

On August 18, 2016, we published a **Federal Register** notice inviting the public to comment on an application for a permit to conduct scientific research on biological samples from olive ridley sea turtle (*Lepidochelys olivacea*), however the species should have been identified as Kemp's ridley sea turtle (*Lepidochelys kempii*) (81 FR 55224). We are now reopening the comment period to allow the public the opportunity to review this new information. This notification covers activities to be conducted by the applicant over a 1-year period.

Sandy Thomas, Egg Harbor Township, NJ; PRT–93219B

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species to enhance species propagation or survival: Blue-throated macaw (*Ara glaucogularis*), Golden parakeet (*Guarouba guarouba*), Red-fronted macaw (*Ara rubrogenys*), and Citron-crested cockatoo (*Cacatua sulphurea citrinocristata*). This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Harvard University, Museum of Comparative Zoology, Cambridge, MA; PRT–090287

The applicant requests renewal of their permit to export and reimport nonliving museum specimens of endangered and threatened species previously accessioned into the applicant's collection for scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Multiple Applicants

The following applicants each request a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Scott Rider, Charleston, SC; PRT–02924C

Applicant: Harrison Swain, Beaumont, TX; PRT–01844C

Applicant: Walter Maximuck, Stockton, NJ; PRT–04172C

Applicant: Mychal Murray, Houston, TX; PRT–02406C

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2016–22323 Filed 9–15–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[167A2100DD.AADD001000.A0E501010.999900]

Reinstate Agency Information Collection for the Johnson O'Malley Act Requirements

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Reinstate information collection and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Bureau of Indian Education is seeking comments and will ask the Office of Management and Budget (OMB) for approval to reinstate the collection of information, Johnson O'Malley Act Requirements, 25 CFR 273, previously authorized by OMB Control Number 1076–0096.

DATES: Submit comments on or before November 15, 2016.

ADDRESSES: You may submit comments on the information collection to Ms. Juanita Mendoza, Program Analyst, Bureau of Indian Education, U.S. Department of the Interior, 1849 C Street NW., MS: #4656 MIB, Washington, DC 20240; or email to: *Juanita.Mendoza@bie.edu*. Please mention that your comments concern the Johnson O'Malley Act Requirements, OMB Control Number 1076–0096.

FOR FURTHER INFORMATION CONTACT: To request a copy of the information collection request, any explanatory information, and related material, see the contact information provided in the **ADDRESSES** section above.

SUPPLEMENTARY INFORMATION:

I. Abstract

This information collection was authorized for several years under OMB Control Number 1076–0096. In 2005, the information collection was discontinued. However, the Bureau of Indian Education (BIE) would like to reinstate this collection of information for the reasons described below.

The Johnson O'Malley Act (JOM), 25 U.S.C. 455–457, authorizes the BIE to enter into contracts for the purpose of financially assisting those efforts designed to meet the specialized and unique educational needs of eligible Indian students enrolled in public schools and previously private schools. The JOM programs offered to American Indian and Alaska Native students vary and may include such programs as culture, language, academics, and dropout prevention. These include programs supplemental to the regular school program and school operational support, where such support is necessary to maintain established State educational standards.

The information allows the BIE to obtain the information necessary to determine applicant eligibility, evaluate applicant education plans, and review annual reports submitted by States, school districts, Indian corporations, and Tribal organizations who apply for and enter into contracts for the JOM Program. For purposes of this information collection, only State, school district, Indian corporations, and Tribal organizations are required to submit an application to determine eligibility to receive JOM Program funds. Federally recognized Tribes who wish to participate in the JOM Program are able to apply for funding under the Indian Self-Determination and Education Assistance Act Programs, 25 CFR 900, OMB Control Number 1076–0136.

The regulations at 25 CFR 273, Johnson O'Malley Act, implement the Act. The information collected is subject to the system of records notice "Native American Student Information System, BIA–22" referenced as 73 FR 40605 dated July 15, 2008. The burden hours for this new collection of information are reflected in the Estimated Total Annual Hour Burden in this notice.

II. Request for Comments

The BIE requests your comments on this collection concerning: (a) The necessity of this information collection for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) The accuracy of the agency's estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) Ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) Ways we could minimize the burden of the collection of the information on the respondents.

Please note that an agency may not conduct or sponsor, and an individual need not respond to, a collection of information unless it displays a valid OMB Control Number.

It is our policy to make all comments available to the public for review at the location listed in the **ADDRESSES** section. Before including your address, phone number, email address or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

III. Data

OMB Control Number: 1076–0096.

Title: Johnson O'Malley Act Requirements, 25 CFR 273.

Brief Description of Collection: Submission of this information allows a State, school district, Indian Corporation, or Tribal organization to enter into a contract with BIE for JOM program funds to financially assist efforts designed to meet the specialized and unique education needs of eligible Indian students enrolled in public schools and previously private schools.

Type of Review: Reinstatement.

Respondents: State, school district, Indian Corporations, and Tribal organizations.

Number of Respondents: 800 per year.

Estimated Number of Responses: 800 per year.

Estimated Time per Response: 5 hours.

Frequency of Response: Annually.

Obligation To Respond: A response if required to obtain or maintain a benefit.

Estimated Total Annual Hour Burden: 4,000 hours.

Estimated Total Annual Non-Hour Dollar Cost: $0.

Elizabeth K. Appel,

Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2016–22317 Filed 9–15–16; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLORB00000.L17110000.PH0000 .LXSSH1060000.16XL1109AF; HAG 16–0221]

Notice of Public Meeting for the Steens Mountain Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, and the U.S. Department of the Interior, Bureau of Land Management (BLM), the Steens Mountain Advisory Council (SMAC) will meet as indicated below:

DATES: Thursday, September 29, 2016 from 9 a.m. to 5 p.m., and Friday, September 30, 2016 from 8:30 a.m. to 2 p.m., at the BLM's Burns District Office, 28910 Hwy 20 W, in Hines, Oregon. Daily sessions may end early if all business items are accomplished ahead of schedule, or go longer if discussions warrant more time.

FOR FURTHER INFORMATION CONTACT: Tara Thissell, Public Affairs Specialist, BLM Burns District Office, 28910 Highway 20 West, Hines, Oregon 97738, (541) 573–4519, or email *tthissell@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1(800) 877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The SMAC was initiated August 14, 2001, pursuant to the Steens Mountain Cooperative Management and Protection Act of 2000 (Pub. L. 106–399). The SMAC provides representative counsel and advice to the BLM regarding new and unique approaches to management of the land within the bounds of the Steens Mountain Cooperative Management and Protection Area, recommends cooperative programs and incentives for landscape management that meet human needs, and advises the BLM on maintenance and improvement of the ecological and economic integrity of the area. Agenda items for the September 29 and 30 session include: Discussions regarding the Steens Mountain No Livestock Grazing Area Fencing and Inholder Access Envionmental Assessments; the Steens Mountain Running Camp Special Recreation Use Permit; and public access in the Pike Creek Canyon Area; updates from the Andrews/Steens Resource Area Field Manager and the Recreation, Wildfire and Wild Horse and Burro Program; and regular business items such as approving the previous meeting's minutes, member round-table, and planning the next meeting's agenda. Any other matters that may reasonably come before the SMAC may also be addressed. Public comment periods are available each day. Unless otherwise approved by the SMAC Chair, the public comment period will last no longer than 30 minutes, and each speaker may address the SMAC for a maximum of five minutes. The public is welcome to attend all sessions.

Rhonda Karges,

Andrews/Steens Resource Area Field Manager.

[FR Doc. 2016–22292 Filed 9–15–16; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLOR957000–L14400000–BJ0000–16XL1109AF; HAG 16–0222]

Filing of Plats of Survey: Oregon/Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The plats of survey of the following described lands are scheduled to be officially filed in the Bureau of Land Management, Oregon State Office, Portland, Oregon, 30 days from the date of this publication.

Willamette Meridian

Oregon
- T. 34 S., R. 2 E., accepted August 23, 2016

Washington
- T. 20 N., R. 4 E., accepted August 23, 2016
- T. 21 N., R. 3 W., accepted August 23, 2016
- T. 15 N., R. 26 E., accepted September 2, 2016

ADDRESSES: A copy of the plats may be obtained from the Public Room at the Bureau of Land Management, Oregon State Office, 1220 SW 3rd Avenue, Portland, Oregon 97204, upon required payment.

FOR FURTHER INFORMATION CONTACT: Kyle Hensley, (503) 808–6124, Branch of Geographic Sciences, Bureau of Land Management, 1220 SW 3rd Avenue, Portland, Oregon 97204. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: A person or party who wishes to protest against this survey must file a written notice with the Oregon State Director, Bureau of Land Management, stating that they wish to protest. A statement of reasons for a protest may be filed with the notice of protest and must be filed with the Oregon State Director within thirty days after the protest is filed. If a protest against the survey is received prior to the date of official filing, the filing will be stayed pending consideration of the protest. A plat will not be officially filed until the day after all protests have been dismissed or otherwise resolved. Before including your address, phone number, email address, or other personally identifying information in your comment, you should be aware that your entire comment—including your personally identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personally identifying information from public review, we cannot guarantee that we will be able to do so.

Mary J.M. Hartel,

Chief Cadastral Surveyor of Oregon/Washington.

[FR Doc. 2016–22295 Filed 9–15–16; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLES964000.L54100000.FR0000]

Notice of Realty Action: Application for Conveyance of Federally Owned Mineral Interests in Escambia County, FL

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action.

SUMMARY: The Bureau of Land Management (BLM) is processing an application under the Federal Land Policy and Management Act of October 21, 1976 (FLPMA) to convey the undivided mineral interest owned by the United States in 70 acres located in Escambia County, Florida, to the surface owner, Airway Development, LLC. Publication of this notice temporarily segregates the federally owned mineral interests in the land covered by the application from all forms of appropriation under the public land laws, including the mining laws, for up to 2 years while the BLM processes the application.

DATES: Interested persons may submit written comments to the BLM at the address listed below. Comments must be received no later than October 31, 2016.

ADDRESSES: Bureau of Land Management, Eastern States State Office, 20 M Street SE., Suite 950, Washington, DC 20003. Detailed information concerning this action is available for review at this address.

FOR FURTHER INFORMATION CONTACT: Frankie Morgan, Land Law Examiner, by telephone at 202–912–7738 or by email at *fmorgan@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individuals during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question for the above individuals. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Airway Development, LLC, the surface owner, has applied to purchase federally owned mineral interests located in Escambia County, Florida, described as follows:

The South 1155′ of the Southwest Quarter of the Northeast Quarter and the South 1155′ of the Southeast Quarter of the Northwest Quarter, all lying in Section 12, Township 1 South, Range 30 West, Escambia County, Florida.

The area described contains 70.00 acres.

Under certain conditions, Section 209(b) of FLPMA authorizes conveyance of the federally owned mineral interests in land to the current or prospective surface owner. As required under Section 209(3)(i) of FLPMA, the applicant deposited a sum of money determined sufficient to cover administrative costs including, but not limited to, the cost for the Mineral Potential Report. The objective of Section 209 is to allow consolidation of the surface and mineral interests when either one of the following conditions exist: (1) There are no known mineral values in the land; or (2) where continued Federal ownership of the mineral interests interferes with or precludes appropriate non-mineral development and such development is a more beneficial use of the land than mineral development. Airway Development, LLC, filed an application for the conveyance of federally owned mineral interests in the above-described tract of land. Subject to valid existing rights, on September 16, 2016 the federally owned mineral interests in the lands described above are hereby segregated from all forms of appropriation under the public land laws, including the mining laws, while the application is being processed to determine if either one of the two specified conditions exists and, if so, to otherwise comply with the procedural requirements of 43 CFR part 2720. The segregation shall terminate upon: (1) Issuance of a patent or other document of conveyance as to such mineral interests; (2) final rejection of the application; or (3) on September 17, 2018, whichever occurs first. Please submit all comments in writing to the individuals at the address listed above.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made available to the public at any time. While you can ask in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 CFR 2720.1–1(b).

Karen Mouritsen,
State Director.

[FR Doc. 2016–22415 Filed 9–15–16; 8:45 am]

BILLING CODE 4310–GJ–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–21643; PPWOCRADP2, PCU00RP14.R50000]

National Historic Landmarks Committee of the National Park System Advisory Board Meeting

AGENCY: National Park Service, Interior.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Committee Act (5 U.S.C. Appendix 1–16), and Part 65 of title 36 of the Code of Federal Regulations, that a meeting of the National Historic Landmarks Committee of the National Park System Advisory Board will be held beginning at 10:00 a.m. on October 18, 2016, at the Charles Sumner School Museum and Archives. The meeting will continue beginning at 9:30 a.m. on October 19, 2016.

DATES: The meeting will be held on Tuesday, October 18, 2016, from 10:00 a.m. to 4:30 p.m.; and Wednesday, October 19, 2016, from 9:30 a.m. to 4:30 p.m. (EASTERN).

LOCATION: The Charles Sumner School Museum and Archives, 3rd Floor, The Richard L. Hurlbut Memorial Hall, 1201 17th Street NW., Washington, DC 20036.

Agenda: The National Park System Advisory Board and its National Historic Landmarks Committee may consider the following nominations:

ALASKA

Matanuska Colony Historic District, Palmer
Walrus Island Archeological District, Dillingham Census Area

ARIZONA

Painted Desert Community Complex, Petrified Forest National Park, Apache County

CALIFORNIA

Our Lady of Guadalupe Mission Chapel, San Jose

DELAWARE

George Read II House, New Castle

INDIANA

West Union Bridge, Parke County

NEBRASKA

Omaha Union Station, Omaha

NEW YORK

Davis–Ferris Organ, Village of Round Lake
Franklin D. Roosevelt Library, Hyde Park

NORTH CAROLINA

Pauli Murray Family Home, Durham

NORTH DAKOTA

Biesterfeldt Site, Ransom County

OHIO

Eldean Bridge, Miami County
May 4, 1970, Kent State Shootings Site, Kent

PENNSYLVANIA

W. A. Young and Sons Foundry And Machine Shop, Rices Landing

Proposed Amendments to Existing Designations:

LOUISIANA

Maison Olivier, St. Martinville (name change and updated documentation)

NEW YORK

Hamilton Grange, New York (updated documentation)

VIRGINIA

Ball's Bluff Battlefield Historic District, Leesburg (updated documentation and boundary change)
Virginia State Capitol, Richmond (name change and updated documentation)

FOR FURTHER INFORMATION CONTACT: Patricia Henry, Historian, National Historic Landmarks Program, National Park Service, 1849 C Street NW., Washington, DC 20240, telephone (202) 354–2216, or email: *Patty_Henry@nps.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the meeting of the National Historic Landmarks Committee of the National Park System Advisory Board is to evaluate nominations of historic properties in order to advise the National Park System Advisory Board of the qualifications of each property being proposed for National Historic Landmark designation, and to make recommendations regarding the possible designation of those properties as National Historic Landmarks to the National Park System Advisory Board at their meeting on November 17–18, 2016, in Philadelphia, Pennsylvania. The Committee also makes recommendations to the National Park System Advisory Board regarding amendments to existing designations and proposals for withdrawal of designation. The members of the National Historic Landmarks Committee are:

Dr. Stephen Pitti, Chair
Dr. James M. Allan
Dr. Cary Carson
Dr. Yong Chen
Mr. Douglas Harris
Ms. Mary Hopkins
Mr. Luis Hoyos, AIA
Dr. Sarah A. Leavitt
Dr. Barbara J. Mills
Dr. Michael E. Stevens
Dr. Amber Wiley
Dr. David Young

The meeting will be open to the public. Pursuant to 36 CFR part 65, any member of the public may file, for consideration by the National Historic Landmarks Committee of the National Park System Advisory Board, written comments concerning the National Historic Landmarks nominations, amendments to existing designations, or proposals for withdrawal of designation.

Comments should be submitted to J. Paul Loether, Chief, National Historic Landmarks Program and National Register of Historic Places, National Park Service, 1849 C Street NW., Washington, DC 20240, email: *Paul_Loether@nps.gov.*

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Alma Ripps,
Chief, Office of Policy.

[FR Doc. 2016–22351 Filed 9–15–16; 8:45 am]

BILLING CODE 4310–EE–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–21817; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Washington State Parks and Recreation Commission, Olympia, WA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Washington State Parks and Recreation Commission [hereafter State Parks], has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the State Parks. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the State Parks at the address in this notice by October 17, 2016.

ADDRESSES: Alicia Woods, Washington State Parks and Recreation Commission, P.O. Box 42650, Olympia, WA 98504–2650, telephone (360) 902–0939, email *Alicia.Woods@parks.wa.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the State Parks. The human remains and associated funerary objects were removed from Cama Beach State Park, Island County, WA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the State Parks professional staff in consultation with representatives of the Stillaguamish Tribe of Indians of Washington (previously listed as the Stillaguamish Tribe of Washington); Swinomish Indian Tribal Community (previously listed as the Swinomish Indians of the Swinomish Reservation of Washington); Tulalip Tribes of Washington (previously listed as the Tulalip Tribes of the Tulalip Reservation of Washington); and Upper Skagit Indian Tribe.

History and Description of the Remains

Between 2004 and 2006, human remains representing, at minimum, three individuals were removed from the Cama Beach Shell Midden Site on Camano Island in Island County, WA. No known individuals were identified. The 483 associated funerary objects are 170 lots of unmodified shell, 1 perforated shell, 124 lots of unmodified bone, 8 modified bone objects, 73 lots of fire modified rock, 13 stone tools, 1 modified wood object, 3 lots of ochre, 42 lots of charcoal, 30 lots of bulk material, 16 historic objects, and 2 lots of botanical material.

Between 2002 and 2006, State Parks contracted Cascadia Archaeology to survey and subsequently perform excavation and data recovery of site 45–IS–2 for the purposes of upgrading sewer and utility lines. Historically the site is a 1930s–1980s fishing and vacation resort with cabins for visitors and housing for owners and management. During excavation and data recovery it was determined the site's prehistoric use was as a seasonal Native American fishing site. During the survey and excavation phases of the project four burials were discovered. The burials were left in-situ and avoided per the request of tribal representatives in consultation with State Parks' staff on-site. The human remains and funerary objects listed in this notice were identified as human in the lab during the analysis phase between 2005 and 2008.

Camano Island is located in Puget Sound between Whidbey Island and mainland Washington State; the Cama Beach Shell Midden site is on the western shores of the island. Saratoga Passage is a waterway between the two islands. Along Saratoga Passage, the shores of both islands are rich in prehistoric Native American seasonal resources sites.

Historical and anthropological sources indicate that the Kikiallus, Swinomish, Lower Skagit and Stillaguamish peoples occupied, and had village sites in, the Penn Cove area of Whidbey Island and on the northwestern shore of Camano Island. The Snohomish people (a predecessor group to, and represented by, the present-day Tulalip Tribes of Washington) had a permanent village at the southernmost end of the island.

Through kinship ties and alliances, and by invitation, the Kikiallus, Upper Skagit, Lower Skagit, Snohomish, Stillaguamish, and Swinomish peoples utilized the waterways, resource grounds, and the beaches of Camano and Whidbey Islands. These peoples shared the same language, and maintained similar economic traditions, social and ceremonial customs, as well as trade and defense alliances.

State Parks staff has determined these human remains and associated funerary objects to be culturally affiliated with the Stillaguamish Tribe of Indians of Washington (previously listed as the Stillaguamish Tribe of Washington); the Swinomish Indian Tribal Community (previously listed as the Swinomish Indians of the Swinomish Reservation of Washington); the Tulalip Tribes of Washington (previously listed as the Tulalip Tribes of the Tulalip Reservation of Washington); and the Upper Skagit Indian Tribe.

Determinations Made by the Washington State Parks and Recreation Commission

Officials of the Washington State Parks and Recreation Commission have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of, at minimum, three individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 483 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and the Stillaguamish Tribe of Indians of Washington (previously listed as the Stillaguamish Tribe of Washington); Swinomish Indian Tribal Community (previously listed as the Swinomish Indians of the Swinomish Reservation of Washington); Tulalip Tribes of Washington (previously listed as the Tulalip Tribes of the Tulalip Reservation of Washington); and Upper Skagit Indian Tribe, Washington.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Alicia Woods, Washington State Parks and Recreation Commission, P.O. Box 42650, Olympia, WA 98504–2650, telephone (360) 902–0939, email *Alicia.Woods@parks.wa.gov,* by October 17, 2016. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Stillaguamish Tribe of Indians of Washington (previously listed as the Stillaguamish Tribe of Washington); the Swinomish Indian Tribal Community (previously listed as the Swinomish Indians of the Swinomish Reservation of Washington); the Tulalip Tribes of Washington (previously listed as the Tulalip Tribes of the Tulalip Reservation of Washington); and the Upper Skagit Indian Tribe may proceed.

The State Parks is responsible for notifying the Stillaguamish Tribe of Indians of Washington (previously listed as the Stillaguamish Tribe of Washington); the Swinomish Indian Tribal Community (previously listed as the Swinomish Indians of the Swinomish Reservation of Washington); the Tulalip Tribes of Washington (previously listed as the Tulalip Tribes of the Tulalip Reservation of Washington); and the Upper Skagit Indian Tribe that this notice has been published.

Dated: August 23, 2016.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2016–22313 Filed 9–15–16; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–21820; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Tennessee Valley Authority, Knoxville, TN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Tennessee Valley Authority (TVA) has completed an inventory of human remains and associated funerary objects in consultation with the appropriate federally recognized Indian tribes, and has determined that a cultural affiliation between the human remains and associated funerary objects and any present-day federally recognized Indian tribes cannot be reasonably traced. Representatives of any federally recognized Indian tribe not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to TVA. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the federally recognized Indian tribe stated in this notice may proceed.

DATES: Representatives of any federally recognized Indian tribe not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to TVA at the address in this notice by October 17, 2016.

ADDRESSES: Dr. Thomas O. Maher, TVA, 400 West Summit Hill Drive, WT11D, Knoxville TN 37902–1401, telephone (865) 632–7458, email *tomaher@tva.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of TVA. The human remains and associated funerary objects were removed from archeological sites in Jackson and Marshall Counties, AL.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains and associated funerary objects was made by TVA professional staff in consultation with the University of Alabama and representatives of the Alabama-Coushatta Tribe of Texas (previously listed as the Alabama-Coushatta Tribes of Texas); Alabama-Quassarte Tribal Town; Cherokee Nation; Coushatta Tribe of Louisiana; Eastern Band of Cherokee Indians; Eastern Shawnee Tribe of Oklahoma; Poarch Band of Creeks (previously listed as the Poarch Band of Creek Indians of Alabama); The Chickasaw Nation; The Choctaw Nation of Oklahoma; The Muscogee (Creek) Nation; Thlopthlocco Tribal Town; and the United Keetoowah Band of Cherokee Indians in Oklahoma.

History and Description of the Remains

The sites listed in this notice were excavated as part of TVA's Guntersville Reservoir project by the Alabama Museum of Natural History (AMNH) at the University of Alabama, using labor and funds provided by the Works Progress Administration. Details regarding these excavations and sites may be found in a report, *An Archaeological Survey of Guntersville Basin on the Tennessee River in Northern Alabama,* by William S. Webb and Charles G. Wilder. The human remains and associated funerary objects listed in this notice have been in the physical custody of the AMNH at the University of Alabama since excavation but are under the control of TVA.

From January to April 1939, human remains representing, at minimum, 30 individuals were removed from the Crow Creek Island site, 1JA155, in Jackson County, AL. Excavations commenced after TVA acquired this land on June 30, 1938. Excavations revealed multiple occupations including Middle Woodland (Copena phase), Late Woodland (Flint River phase), and Mississippian (Crow Creek phase). The human remains include adults, juveniles, and infants of both sexes. No known individuals were identified. The 50 associated funerary objects include 48 shell beads, 1 shell ear plug, and 1 ground stone steatite bowl.

From October 1938 to January 1939, human remains representing, at minimum, 44 individuals were removed from the Sublet Ferry site, 1JA102, three miles southeast of Hollywood in Jackson County, AL. Excavation commenced after TVA acquired a permit for archeological exploration on June 11, 1938. This land was subsequently purchased on October 17, 1938. Excavations revealed this to be a shell midden overlying a dark midden soil. Both Woodland and Mississippian occupations were identified. The human remains include adults, juveniles, and children of both sexes. No known individuals were identified. The 27 associated funerary objects include 24 shell barrel beads, 1 Hamilton projectile point, 1 bone pin, and 1 bone awl.

From June 11 to 23, 1938, human remains representing, at minimum, six individuals were removed from the Langston site, 1JA9, in Jackson County, AL. Excavation commenced after TVA had purchased the land encompassing it on December 30, 1936. The site, eight miles southeast of Scottsboro, AL, was composed of a mound (designated 1JA9a) and a village. These brief excavations focused on the low mound. Artifacts from the mound and surrounding village indicate both a Woodland and Mississippian occupation. The human remains include adults, juveniles, and an infant of indeterminate sex. No known individuals were identified. The 22 associated funerary objects are fragments of a copper ornament associated with one of these individuals.

From November 21 to 29, 1938, human remains representing, at minimum, two individuals were removed from site 1MS106, 11 miles northeast of the city of Guntersville in Marshall County, AL. Excavation commenced after TVA purchased the land on April 21, 1937. Little is known about this site except a one paragraph reference to the excavation in a progress report which indicates it was a rapid exploration that recovered three burials. Further, ceramics from this site indicate occupations during both the Woodland and Mississippian periods. The culturally unidentifiable human remains are of two adult males. No known individuals were identified. No associated funerary objects are present.

From December 10, 1936, to February 2, 1937, human remains representing, at minimum, four individuals were removed from the Cartright site, 1MS109, 11 miles northeast of the city of Guntersville in Marshall County, AL. Excavation commenced shortly before TVA purchased the land on April 21, 1937. Evidence at the surface indicated that this site was 50 x 60 feet with four underlying strata. Ceramics from this site indicate occupations during both the Woodland and Mississippian periods. The human remains are of one child of indeterminate sex and three adults, two of which are female. No known individuals were identified. No associated funerary objects are present.

From October 25 to December 7, 1938, human remains representing, at minimum, four individuals were removed from the Stephenson site, 1MS111, 11 miles northeast of the city of Guntersville in Marshall County, AL. Excavation commenced after TVA purchased the land on April 21, 1937. Limited excavation in the village area revealed three underlying strata. Steatite stone vessel sherds in the lowest strata indicate a Late Archaic occupation. Further, ceramics from the upper strata of this site indicate occupations during both the Late Woodland and Mississippian periods. The human remains are of one child of indeterminate sex and three adults, two of which are female. No known individuals were identified. No associated funerary objects are present.

From June 1938 to May 1939, human remains representing, at minimum, 261 individuals were removed from the Columbus City Landing site, 1MS91, 9 miles northeast of the city of Guntersville in Marshall County, AL. Excavation commenced after TVA purchased the land on March 8, 1937. There were excavations in both the village (Unit I) and adjacent mounds (Unit II). Artifacts recovered from this excavation revealed that the primary occupations were during the Middle Woodland (A.D. 100–500), Mississippian (A.D. 1200–1500), and historic periods. The human remains include adults, juveniles, children, and infants of both sexes. No known individuals were identified. The 214 associated funerary objects include 7 glass beads; 1 biface; 4 bone bodkins; 3 bone pins; 2 copper bangles; 1 Hilabee Schist celt; 15 pieces of clay (unfired); 4 clay foot rests; 2 clay head rests; 1 copper axe head; 2 copper coil earbobs; 7 copper ear spools; 2 copper reel gorgets; 51 galena nodules; 1 ground hematite; 62 Long Branch Fabric Marked sherds; 1 Mississippi Plain sherd disk fragment; 1 Mud Creek projectile point or knife; 24 Mulberry Creek Plain sherds; 2 projectile points or knives; 1 red ochre; 6 rolled copper tubular beads; 2 shell beads; 2 shell ear bobs; 1 shell gorget; 3 tempered clay samples; 1 wood fragment; 1 shell fragment; 2 unmodified hematite fragments; 1 yellow clay sample and 1 yellow pigment.

TVA determined that cultural affiliation between human remains and associated funerary objects and any present day federally recognized tribes cannot be reasonably traced. Accordingly, these items are culturally unidentifiable and TVA intends to transfer control of these items pursuant to 43 CFR 10.11(c).

At the time of the excavation and removal of these human remains and associated funerary objects, the land from which the remains and objects were removed was not the tribal land of any federally recognized Indian tribe. On March 10, 2016, TVA consulted with all federally recognized Indian tribes who are recognized as aboriginal to the area from which these Native American human remains and associated funerary objects were removed. These tribes are the Cherokee Nation, Eastern Band of Cherokee Indians, and United Keetoowah Band of Cherokee Indians in Oklahoma. None of these Indian tribes agreed to accept control of the human remains and associated funerary objects. After further consultation with the parties that were a part of this overall consultation, TVA has decided to transfer control of the human remains and associated funerary objects to the Alabama-Coushatta Tribe of Texas, the Alabama-Quassarte Tribal Town, the Coushatta Tribe of Louisiana, and the Muscogee (Creek) Nation.

Determinations Made by the Tennessee Valley Authority

Officials of TVA have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 351 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 313 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and associated funerary objects and any present-day Indian tribe.
- Pursuant to 43 CFR 10.11(c)(1)(i), at the time of excavation of the human remains and associated funerary objects, the land from which the cultural items were removed was not the tribal land of any federally recognized Indian tribe.
- Pursuant to 43 CFR 10.11(c)(1)(ii), the following tribes are aboriginal to the area from which the cultural items were excavated: Cherokee Nation, Eastern Band of Cherokee Indians, and the United Keetoowah Band of Cherokee Indians in Oklahoma. None of these tribes agreed to accept control of the human remains or associated funerary objects.
- Pursuant to 43 CFR 10.11(c)(2)(i), TVA has decided to transfer control of the culturally unidentifiable human remains to the Alabama-Coushatta Tribe of Texas, the Alabama-Quassarte Tribal Town, the Coushatta Tribe of Louisiana, and the Muscogee (Creek) Nation.
- Pursuant to 43 CFR 10.11(c)(4), TVA has decided to transfer control of the culturally unidentifiable associated funerary objects to the Alabama-Coushatta Tribe of Texas, the Alabama-Quassarte Tribal Town, the Coushatta Tribe of Louisiana, and the Muscogee (Creek) Nation.

Additional Requestors and Disposition

Representatives of any federally recognized Indian tribe not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Dr. Thomas O. Maher, TVA, 400 West

Summit Hill Drive, WT11D, Knoxville, TN 37902–1401, telephone (865) 632–7458, email *tomaher@tva.gov,* by October 17, 2016. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Alabama-Coushatta Tribe of Texas, the Alabama-Quassarte Tribal Town, the Coushatta Tribe of Louisiana, and the Muscogee (Creek) Nation may proceed.

TVA is responsible for notifying the Alabama-Coushatta Tribe of Texas (previously listed as the Alabama-Coushatta Tribes of Texas); Alabama-Quassarte Tribal Town; Cherokee Nation; Coushatta Tribe of Louisiana; Eastern Band of Cherokee Indians; Eastern Shawnee Tribe of Oklahoma; Poarch Band of Creeks (previously listed as the Poarch Band of Creek Indians of Alabama); The Chickasaw Nation; The Choctaw Nation of Oklahoma; The Muscogee (Creek) Nation; Thlopthlocco Tribal Town; and the United Keetoowah Band of Cherokee Indians in Oklahoma that this notice has been published.

Dated: August 23, 2016.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2016–22315 Filed 9–15–16; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–21818; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Washington State Parks and Recreation Commission, Olympia, WA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Washington State Parks and Recreation Commission (hereafter State Parks), in consultation with the appropriate Indian tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of sacred objects. Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the State Parks. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the State Parks at the address in this notice by October 17, 2016.

ADDRESSES: Alicia Woods, Washington State Parks and Recreation Commission, P.O. Box 42650, Olympia, WA 98504–2650, telephone (360) 902–0939, email *Alicia.Woods@parks.wa.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the State Parks that meet the definition of sacred objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

Between 2004 and 2006, six sacred objects were removed from the Cama Beach Shell Midden (45–IS–2) in Island County, WA. State Parks contracted Cascadia Archaeology to perform excavation and data recovery of site 45–IS–2 for the purposes of upgrading sewer and utility lines. Historically the site is a 1930s-1980s fishing and vacation resort, with cabins for visitors and housing for owners and management, most of which still stand. During excavation and data recovery it was determined the site's prehistoric use was as a seasonal Native American fishing site. Both prehistoric and historic material was recovered from the site. Among the material were 3 complete and 3 fragmentary, culturally modified (perforated) Weathervane scallop shells.

According to research, the scallop shells were incorporated into a rattle that would have been one of the cleansing devices used by a dancer in a ceremony of ritual purification during times of change or crisis. The rattles were passed down through families. The rattles are also known to have been used in cleansing ceremonies by shamans. Once identified, the objects remained in Cascadia Archaeology's custody until the overall collection of site material was transferred to the State Parks in 2009.

Camano Island is located in Puget Sound between Whidbey Island and mainland Washington State; the Cama Beach Shell Midden site is on the western shores of the island. Saratoga Passage is a waterway between the two islands. Along Saratoga Passage, the shores of both islands are rich in prehistoric Native American seasonal resources sites.

Historical and anthropological sources indicate that the Kikiallus, Swinomish, Lower Skagit and Stillaguamish peoples occupied and had village sites in the Penn Cove area of Whidbey Island and on the northwestern shore of Camano Island. The Snohomish people (a predecessor group to, and represented by, the Tulalip Tribes of Washington) had a permanent village at the southernmost end of the island.

Through kinship ties and alliances and by invitation the Kikiallus, Upper Skagit, Lower Skagit, Snohomish, Stillaguamish, Snohomish, and Swinomish peoples utilized the waterways, resource grounds, and the beaches of Camano and Whidbey Islands. These peoples shared the same language, and maintained similar economic traditions, social and ceremonial customs, as well as trade and defense alliances.

Based on historical and anthropological sources, State Parks staff has determined these sacred objects are culturally affiliated with the Stillaguamish Tribe of Indians of Washington (previously listed as the Stillaguamish Tribe of Washington); the Swinomish Indian Tribal Community (previously listed as the Swinomish Indians of the Swinomish Reservation of Washington); the Tulalip Tribes of Washington (previously listed as the Tulalip Tribes of the Tulalip Reservation, Washington); and the Upper Skagit Indian Tribe.

Determinations Made by the Washington State Parks and Recreation Commission

Officials of the State Parks have determined that:

- Pursuant to 25 U.S.C. 3001(3)(C), the 6 cultural items described above are specific ceremonial objects needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the sacred objects and the Stillaguamish Tribe of Indians of Washington (previously listed as the Stillaguamish Tribe of Washington); the

Swinomish Indian Tribal Community (previously listed as the Swinomish Indians of the Swinomish Reservation of Washington); the Tulalip Tribes of Washington (previously listed as the Tulalip Tribes of the Tulalip Reservation, Washington); and the Upper Skagit Indian Tribe.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Alicia Woods, Washington State Parks and Recreation Commission, PO Box 42650, Olympia, WA 98504–2650, telephone (360) 902–0939, email *Alicia.Woods@parks.wa.gov,* by October 17, 2016. After that date, if no additional claimants have come forward, transfer of control of the sacred objects to the Stillaguamish Tribe of Indians of Washington (previously listed as the Stillaguamish Tribe of Washington); the Swinomish Indian Tribal Community (previously listed as the Swinomish Indians of the Swinomish Reservation of Washington); the Tulalip Tribes of Washington (previously listed as the Tulalip Tribes of the Tulalip Reservation, Washington); and the Upper Skagit Indian Tribe, may proceed.

The State Parks is responsible for notifying the Stillaguamish Tribe of Indians of Washington (previously listed as the Stillaguamish Tribe of Washington); the Swinomish Indian Tribal Community (previously listed as the Swinomish Indians of the Swinomish Reservation of Washington); the Tulalip Tribes of Washington (previously listed as the Tulalip Tribes of the Tulalip Reservation, Washington); and the Upper Skagit Indian Tribe, that this notice has been published.

Dated: August 23, 2016.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2016–22314 Filed 9–15–16; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–D–COS–POL–21889; PPWODIREP0; PPMPSPD1Y.YM0000]

Notice of November 17–18, 2016, Meeting of the National Park System Advisory Board

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Committee Act, 5 U.S.C. Appendix 1–16, and part 62 of title 36 of the Code of Federal Regulations that the National Park System Advisory Board will meet November 17–18, 2016, in Philadelphia, Pennsylvania. The agenda will include the review of proposed actions regarding the National Historic Landmarks Program. Interested parties are encouraged to submit written comments and recommendations that will be presented to the Board. Interested parties also may attend the board meeting and upon request may address the Board concerning an area's national significance.

DATES: (a) Written comments regarding any proposed National Historic Landmarks matter listed in this notice will be accepted by the National Park Service until November 15, 2016.
(b) The Board will meet on November 17–18, 2016.

ADDRESSES: The meeting will be held in The Liberty View meeting room on the second floor of the Independence Visitor Center, 1 N. Independence Mall W., Philadelphia, Pennsylvania 19106, telephone (215) 965–2300.

Agenda: On the morning of November 17, the Board will convene its business meeting at 8:15 a.m., Eastern Standard Time, and adjourn for the day at 11:30 a.m. On November 18, the Board will reconvene at 8:00 a.m., and adjourn at 5:00 p.m. During the course of the two days, the Board may be addressed by National Park Service Director Jonathan Jarvis and briefed by other NPS officials regarding education, philanthropy, NPS urban initiatives, science, and the NPS Centennial; deliberate and make recommendations concerning National Historic Landmarks Program proposals; and receive status briefings on matters pending before committees of the Board.

FOR FURTHER INFORMATION CONTACT: (a) For information concerning the National Park System Advisory Board or to request to address the Board, contact Shirley Sears, Office of Policy, National Park Service, MC 0004-Policy, 1849 C Street NW., Washington, DC 20240, telephone (202) 354–3955, email *Shirley_Sears@nps.gov.* (b) To submit a written statement specific to, or request information about, any National Historic Landmarks matter listed below, or for information about the National Historic Landmarks Program or National Historic Landmarks designation process and the effects of designation, contact J. Paul Loether, Chief, National Register of Historic Places and National Historic Landmarks Program, National Park Service, 1849 C Street NW. (2280), Washington, DC 20240, email *Paul_Loether@nps.gov.*

SUPPLEMENTARY INFORMATION: Matters concerning the National Historic Landmarks Program will be considered by the Board as follows:

National Historic Landmarks (NHL) Program

NHL Program matters will be considered at the morning session of the business meeting on November 18, during which the Board may consider the following:

Nominations for New NHL Designations

Alaska

- Walrus Islands Archeological District, Dillingham Census Area

Arizona

- Painted Desert Community Complex, Petrified Forest National Park, Apache County

California

- Chicano Park, San Diego
- Neutra Studio and Residences (VDL Research House), Los Angeles
- Our Lady of Guadalupe Mission Chapel, San Jose

Delaware

- George Read II House, New Castle

Indiana

- West Union Bridge, Parke County

Iowa

- Kimball Village Site, Plymouth County

Kansas

- Wyandotte National Burying Ground (Eliza Burton Conley Burial Site), Kansas City

Maryland

- Shifferstadt, Frederick

Mississippi

- Medgar and Myrlie Evers House, Jackson

Nebraska

- Omaha Union Station, Omaha

New York

- Davis-Ferris Organ, Village of Round Lake
- Franklin D. Roosevelt Library, Hyde Park
- New York State Barge Canal Historic District

Albany County

- City of Cohoes
- Colonie
- Cayuga County
- Aurelius
- Brutus
- Cato
- Conquest
- Mentz
- Montezuma

Erie County

- City of Tonawanda
- Amherst
- Tonawanda

Herkimer County

- City of Little Falls
- Danube
- Frankfort
- German Flatts
- Herkimer
- Little Falls
- Manheim
- Ohio
- Russia
- Schuyler
- Village of Frankfort
- Village of Herkimer
- Village of Ilion
- Village of Mohawk

Madison County

- Lenox
- Sullivan

Monroe County

- City of Rochester
- Brighton
- Chili
- Clarkson
- Trenton
- Verona
- Vienna
- Western
- Village of Sylvan Beach

Onondaga County

- City of Syracuse
- Cicero
- Clay
- Elbridge
- Geddes
- Lysander
- Salina
- Van Buren
- Village of Baldwinsville
- Village of Liverpool

Orleans County

- Albion
- Gaines
- Murray
- Ridgeway
- Shelby
- Village of Albion
- Village of Holley
- Village of Medina

Oswego County

- City of Fulton
- City of Oswego
- Constantia
- Granby
- Hastings
- Minetto
- Schroeppel
- Scriba
- Volney
- West Monroe
- Village of Cleveland
- Village of Phoenix

Rensselaer County

- City of Troy
- Schaghticoke

Saratoga County

- City of Mechanicville
- Clifton Park
- Halfmoon
- Moreau
- Northumberland
- Saratoga
- Stillwater
- Waterford
- Village of Schuylerville
- Village of Stillwater
- Village of Waterford

Schenectady County

- City of Schenectady
- Glenville
- Niskayuna
- Rotterdam
- Village of Scotia

Seneca County

- Seneca Falls
- Tyre
- Waterloo
- Village of Waterloo

Washington County

- Easton
- Fort Ann
- Fort Edward
- Greenwich
- Hartford
- Kingsbury
- Whitehall
- Village of Fort Ann
- Village of Fort Edward
- Village of Whitehall

Wayne County

- Arcadia
- Galen
- Lyons
- Macedon
- Palmyra
- Savannah
- Village of Clyde
- Village of Lyons
- Village of Macedon
- Village of Newark
- Village of Palmyra
- Schomburg Center for Research in Black Culture, New York

North Carolina

- Pauli Murray Family Home, Durham

North Dakota

- Biesterfeldt Site, Ransom County

Ohio

- Eldean Bridge, Miami County
- Greenhills Historic District, Greenhills
- May 4, 1970, Kent State Shootings Site, Kent

Pennsylvania

- Keim Homestead, Oley
- W. A. Young and Sons Foundry and Machine Shop, Rices Landing

Texas

- Casa José Antonio Navarro, San Antonio

Wyoming

- Site No. 48GO305, Goshen County

Proposed Amendments to Existing Designations

Indiana

- Indiana War Memorials Historic District, Indianapolis (updated documentation, boundary and name change)

Louisiana

- Maison Olivier, St. Martinvilleb (updated documentation and name change)

New York

- Hamilton Grange, New York (updated documentation)

North Carolina

- Old Salem Historic District, Winston-Salem (updated documentation and boundary change)

Virginia

- Ball's Bluff Battlefield Historic District, Loudoun County (boundary change and updated documentation)
- Virginia State Capitol, Richmond (name change and updated documentation)

Proposed Withdrawal of Designation

Louisiana

- Kate Chopin House, Cloutierville

The board meeting will be open to the public. The order of the agenda may be changed, if necessary, to accommodate travel schedules or for other reasons. Space and facilities to accommodate the public are limited and attendees will be accommodated on a first-come basis. Anyone may file with the Board a written statement concerning matters to be discussed. The Board also will permit attendees to address the Board, but may restrict the length of the presentations, as necessary to allow the Board to complete its agenda within the allotted time. Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Draft minutes of the meeting will be available for public inspection about 12 weeks after the meeting at the Office of Policy, MC 0004-Policy, 1849 C Street NW., Washington, DC.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2016–22349 Filed 9–15–16; 8:45 am]

BILLING CODE 4310–EE–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–AKRO–LACL–ANIA–WRST–GAAR–CAKR–KOVA–21821; PPAKAKROR4; PPMPRLE1Y.LS0000]

Notice of Open Public Meetings for the National Park Service Alaska Region Subsistence Resource Commission Program

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: As required by the Federal Advisory Committee Act (16 U.S.C. Appendix 1–16), the National Park Service (NPS) is hereby giving notice that the Lake Clark National Park Subsistence Resource Commission (SRC), Aniakchak National Monument SRC, Wrangell-St. Elias National Park SRC, Cape Krusenstern National Monument SRC, Kobuk Valley National Park SRC, and Gates of the Arctic National Park SRC will hold public meetings to develop and continue work on NPS subsistence program recommendations, and other related regulatory proposals and resource management issues. The NPS SRC program is authorized under Section 808 of the Alaska National Interest Lands Conservation Act (16 U.S.C. 3118), title VIII.

Lake Clark National Park SRC Meeting/Teleconference Date and Location: The Lake Clark National Park SRC will meet from 1:00 a.m. to 5:00 p.m. or until business is completed on Wednesday, September 28, 2016, at the Community Hall in Nondalton, AK. Teleconference participants must call the National Park Service office at (907) 644–3648, prior to the meeting to receive teleconference passcode information. For more detailed information regarding this meeting, or if you are interested in applying for SRC membership, contact Designated Federal Official Margaret L. Goodro, Superintendent, at (907) 644–3627, or via email at *margaret_goodro@nps.gov,* or Liza Rupp, Subsistence Manager, at (907) 644–3648, or via email at *liza_rupp@nps.gov* or Clarence Summers, Subsistence Manager, at (907) 644–3603 or via email at *clarence_summers@nps.gov.*

Aniakchak National Monument SRC Meeting/Teleconference Date and Location: The Aniakchak National Monument SRC will meet from 2:00 p.m. to 7:30 p.m. or until business is completed on Friday, September 30, 2016, at the Subsistence Building in Chignik Lagoon, AK. Teleconference participants must call the National Park Service at (907) 246–2154 or (907) 246–3305, prior to the meeting for teleconference call in information. For more detailed information regarding this meeting, or if you are interested in applying for SRC membership, contact Linda Chisholm, Subsistence Coordinator, at (907) 246–2154, or via email *linda_chisholm@nps.gov,* or Clarence Summers, Subsistence Manager, at (907) 644–3603, or via email *clarence_summers@nps.gov.*

Wrangell–St. Elias National Park SRC Meeting Dates and Locations: The Wrangell-St. Elias National Park SRC will meet from 10:00 a.m. to 5:00 p.m. or until business is completed on Wednesday, October 12, 2016, at the Northway Village Hall in Northway, AK. On Thursday, October 13, 2016, the Wrangell-St. Elias National Park SRC will meet from 9:00 a.m. to 5:00 p.m. or until business is completed at the Musher's Hall in Tok, AK. For more detailed information regarding these meetings, or if you are interested in applying for SRC membership, contact Barbara Cellarius, Subsistence Coordinator, at (907) 822–7236 or by email at *barbara_cellarius@nps.gov* or Clarence Summers, Subsistence Manager, at (907) 644–3603 or via email at *clarence_summers@nps.gov.*

Gates of The Arctic National Park SRC Meeting Date and Location: The Gates of the Arctic National Park SRC will meet from 9:00 a.m. to 5:00 p.m. or until business is completed on Tuesday, November 15, 2016, and Wednesday, November 16, 2016, at the Gates of the Arctic National Park and Preserve office in Fairbanks, AK. For more detailed information regarding this meeting, or if you are interested in applying for SRC membership, contact Designated Federal Official Greg Dudgeon, Superintendent, at (907) 457–5752, or via email at *greg_dudgeon@nps.gov* or Marcy Okada, Subsistence Coordinator, at (907) 455–0639 or via email at *marcy_okada@nps.gov* or Clarence Summers, Subsistence Manager, at (907) 644–3603, or via email at *clarence_summers@nps.gov.*

Cape Krusenstern National Monument SRC Meeting Date and Location: The Cape Krusenstern National Monument SRC will meet from 1:00 p.m. to 5:00 p.m. or until business is completed on Tuesday, November 8, 2016, and from 9:00 a.m. to 12:00 p.m. on November 9, 2016, at the Northwest Arctic Heritage Center in Kotzebue, AK. For more detailed information regarding this meeting or if you are interested in applying for SRC membership, contact Hannah Atkinson, Cultural Resource Specialist at the Cape Krusenstern National Monument office at (907) 442–4342, or via email at *hannah_atkinson,* or Clarence Summers, Subsistence Manager, at (907) 644–3603 or via email at *clarence_summers@nps.gov.*

Kobuk Valley National Park SRC Meeting Date and Location: The Kobuk Valley National Park SRC will meet from 1:00 p.m. to 5:00 p.m. or until business is completed on Thursday, November 10, 2016, and from 9:00 a.m. to 12:00 p.m. on Friday, November 11, 2016, at the Northwest Arctic Heritage Center in Kotzebue, AK. For more detailed information regarding this meeting or if you are interested in applying for SRC membership, contact Hannah Atkinson, Cultural Resource Specialist at the Kobuk Valley National Park office at (907) 442–4342, or via email at *hannah_atkinson,* or Clarence Summers, Subsistence Manager, at (907) 644–3603 or via email at *clarence_summers@nps.gov.*

Proposed Meeting Agenda: The agenda may change to accommodate SRC business. The proposed meeting agenda for each meeting includes the following:

1. Call to Order—Confirm Quorum
2. Welcome and Introduction
3. Review and Adoption of Agenda
4. Approval of Minutes
5. Superintendent's Welcome and Review of the SRC Purpose
6. SRC Membership Status
7. SRC Chair and Members' Reports
8. Superintendent's Report
9. Old Business
10. New Business
11. Federal Subsistence Board Update
12. Alaska Boards of Fish and Game Update
13. National Park Service Reports
    a. Ranger Update
    b. Resource Manager's Report
    c. Subsistence Manager's Report
14. Public and Other Agency Comments
15. Work Session
16. Set Tentative Date and Location for Next SRC Meeting
17. Adjourn Meeting

SRC meeting locations and dates may change based on inclement weather or exceptional circumstances. If the meeting dates and locations are changed, the Superintendent will issue a press release and use local newspapers and radio stations to announce the rescheduled meeting.

SUPPLEMENTARY INFORMATION: SRC meetings are open to the public and will have time allocated for public testimony. The public is welcome to present written or oral comments to the SRC. SRC meetings will be recorded and meeting minutes will be available upon request from the Superintendent for public inspection approximately six weeks after the meeting. Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Exceptional Circumstance: Pursuant to the Federal Advisory Committee Management Regulations (41 CFR 102–3.150), the notice for this meeting is given less than 15 calendar days prior to the meeting due to exceptional circumstances. Given the exceptional urgency of the events, the agency and advisory committee deemed it important for the advisory committee to meet on the date given to discuss implementation strategies for NPS subsistence collections and plant gathering regulations.

Alma Ripps,
Chief, Office of Policy.

[FR Doc. 2016–22350 Filed 9–15–16; 8:45 am]

BILLING CODE 4310–EE–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[OMB Control Number 1010–0114; MMAA104000]

Information Collection: General Oil and Gas and Sulphur and Production Requirements in the Outer Continental Shelf; Proposed Collection for OMB Review; Comment Request

ACTION: 60-Day notice.

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Ocean Energy Management (BOEM) is inviting comments on a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval. The information collection request (ICR) concerns the paperwork requirements in the regulations under 30 CFR 550, Subparts A, *General;* and K, and *Oil and Gas Production Requirements,* as well as the associated forms. The Office of Management and Budget (OMB) has assigned control number 1010–0114 to this information collection.

DATES: Submit written comments by November 15, 2016.

ADDRESSES: Please send your comments on this ICR to the BOEM Information Collection Clearance Officer, Anna Atkinson, Bureau of Ocean Energy Management, 45600 Woodland Road, Sterling, Virginia 20166 (mail); or *anna.atkinson@boem.gov;* or 703–787–1209 (fax). Please reference OMB Control Number 1010–0114 in your comment and include your name and return address.

FOR FURTHER INFORMATION CONTACT: Anna Atkinson, Office of Policy, Regulations, and Analysis at 703–787–1025 for a copy of the ICR or the forms.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 1010–0114.

Title: 30 CFR 550, Subpart A, *General,* and Subpart K, *Oil and Gas Production Requirements.*

Forms:

- BOEM–0127, Sensitive Reservoir Information Report;
- BOEM–0140, Bottomhole Pressure Survey Report;
- BOEM–1123, Designation of Operator; and
- BOEM–1832, Notification of Incident(s) of Noncompliance.

Abstract: The Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1331 *et seq.* and 43 U.S.C. 1801 *et seq.*), authorizes the Secretary of the Interior to prescribe rules and regulations to administer leasing of the OCS. Such rules and regulations will apply to all operations conducted under a lease. Operations in the OCS must preserve, protect, and develop oil and natural gas resources in a manner that is consistent with the need to make such resources available to meet the Nation's energy needs as rapidly as possible; to balance orderly energy resource development with protection of human, marine, and coastal environments; to ensure the public a fair and equitable return on the resources of the OCS; and to preserve and maintain free enterprise competition. Section 1332(6) states that "operations in the [O]uter Continental Shelf should be conducted in a safe manner by well trained personnel using technology, precautions, and techniques sufficient to prevent or minimize . . . loss of well control . . . physical obstructions to other users of the waters or subsoil and seabed, or other occurrences which may cause damage to the environment or to property or endanger life or health."

The Independent Offices Appropriations Act (31 U.S.C. 9701), the Omnibus Appropriations Bill (Pub. L. 104–133, 110 Stat. 1321, April 26, 1996), and Office of Management and Budget (OMB) Circular A–25 authorize Federal agencies to recover the full cost of services that confer special benefits. Under the Department of the Interior's (DOI) implementing policy, the Bureau of Ocean Energy Management (BOEM) is required to charge fees for services that provide special benefits or privileges to an identifiable non-Federal recipient above and beyond those that accrue to the public.

This information collection request addresses regulations at 30 CFR 550, Subpart A, General, and Subpart K, Oil and Gas Production Requirements, which deal with regulatory requirements of oil, gas, and sulphur operations on the OCS. This request also covers the related Notices to Lessees and Operators (NTLs) that BOEM issues to clarify and provide guidance on some aspects of our regulations, and forms BOEM–0127, BOEM–0140, BOEM–1123, and BOEM–1832.

The BOEM uses the information collected under the Subparts A and K regulations to ensure that operations in the OCS are carried out in a safe and environmentally sound manner, do not interfere with the rights of other users in the OCS, and balance the protection and development of OCS resources. Specifically, we use the information collected to:

- Determine the capability of a well to produce oil or gas in paying quantities or to determine the possible need for additional wells resulting in minimum royalty status on a lease.
- Provide lessees/operators greater flexibility to comply with regulatory requirements through approval of alternative equipment or procedures and departures if they demonstrate equal or better compliance with the appropriate performance standards.
- Ensure that subsurface storage of natural gas does not unduly interfere with development and production operations under existing leases.
- Determine if an application for right-of-use and easement complies with the OCS Lands Act, other applicable laws, and BOEM regulations; and does not unreasonably interfere with the operations of any other lessee.
- Provide for orderly development or disqualification of leases to determine the appropriateness of lessee/operator performance.
- Approve requests to cancel leases and ascertain if/when the Secretary may cancel leases.
- Ensure the protection of any discovered archaeological resources.
- Form BOEM–0127, Sensitive Reservoir Information Report, is used to regulate production rates from sensitive reservoirs. BOEM engineers and geologists use the information for rate control and reservoir studies. The form requests general information about the reservoir and the company, volumetric

data, and fluid analysis and production data.

- Form BOEM–0140, Bottomhole Pressure Survey Report, is used to manage reservoirs in our efforts to conserve natural resources, prevent waste, and protect correlative rights, including the Government's royalty interest. Specifically, BOEM uses the information in reservoir evaluations to determine maximum production and efficiency rates and to review applications for downhole commingling to ensure that action does not harm ultimate recovery or undervalued royalties. The form requests information about the well and operator; test data information such as shut-in time, bottomhole temperature, kelly bushing elevation; and bottomhole pressure points that consist of measured depth(s), true vertical depth(s), pressure(s), and pressure gradient(s).
- Form BOEM–1123, Designation of Operator, records the designation of an operator authorized to act on behalf of the lessee/operating rights owner and to fulfill their obligations under the OCS Lands Act and implementing regulations, or to record the local agent empowered to receive notices and comply with regulatory orders issued. This form requires the respondent to submit general information such as lease number, name, address, company number of designated operator, and signature of the authorized lessee. With this renewal, BOEM will add a signature line on the form to allow for the signature of the company designated as the operator. Also, the current instructions for completing form BOEM–1123 apply only to the Gulf of Mexico region. BOEM would like to require the form to be completed in the same way for all regions, so BOEM has deleted all references to the Gulf of Mexico in the instructions.
- Form BOEM–1832, Notification of Incidents of Non-Compliance (INC), is used to determine that respondents have corrected any Incidents of Non-Compliance identified during compliance reviews. The BOEM issues this form to the operator and the operator then corrects the INC(s), signs and returns the form to the BOEM Regional Supervisor.

We will protect proprietary information according to the Freedom of Information Act (5 U.S.C. 552), it's implementing regulations (43 CFR 2), 30 CFR 252, and 30 CFR 550.197, ''Data and information to be made available to the public or for limited inspection.'' Proprietary information concerning geological and geophysical data will be protected according to 43 U.S.C. 1352. No items of a sensitive nature are collected. Responses are mandatory.

Frequency: Primarily on occasion; monthly.

Description of Respondents: Oil and gas and sulphur lessees/operators.

Estimated Reporting and Recordkeeping Hour Burden: The currently approved annual burden for this collection is 30,635 hours.

The following table details the individual BOEM components and respective hour burden estimates.

BURDEN BREAKDOWN

Citation 30 CFR 550 subpart A and related forms/NTLs	Reporting or recordkeeping requirement	Non-hour cost burdens		
		Hour burden	Average number of annual responses	Annual burden hours
Authority and Definition of Terms				
104; 181; Form BOEM–1832	Appeal orders or decisions; appeal INCs; request hearing due to cancellation of lease.	Exempt under 5 CFR 1320.4(a)(2), (c).		0
Performance Standards				
115; 116	Request determination of well producibility; make available or submit data and information; notify BOEM of test.	5	90 responses	450
119	Apply for subsurface storage of gas; sign storage agreement.	10	3 applications ...	30
Subtotal	....	....	93 responses	480
Cost Recovery Fees				
125; 126; 140	Cost Recovery Fees; confirmation receipt etc; verbal approvals and written request to follow. Includes request for refunds.	Cost Recovery Fees and related items are covered individually throughout this subpart.		0
Designation of Operator				
143	Report change of name, address, etc	Not considered information collection under 5 CFR 1320.3(h)(1).		0
143(a–c); 144; 146; Form BOEM–1123.	Submit designation of operator (Form BOEM–1123—form takes 30 minutes); report updates; notice of termination; submit designation of agent. Request exception. NO FEE.	1	2,584 forms	2,584
143(a–d); 144; 146; Form BOEM–1123.	Change designation of operator (Form BOEM–1123—form takes 30 minutes); report updates; notice of termination; submit designation of agent; include pay.gov confirmation receipt. Request exception. SERVICE FEE.	1	930 forms	930

BURDEN BREAKDOWN—Continued

Citation 30 CFR 550 subpart A and related forms/NTLs	Reporting or recordkeeping requirement	Non-hour cost burdens		
		Hour burden	Average number of annual responses	Annual burden hours
		$175 fee × 930 = $162,750		
186(a)(3); NTL	Apply for user account in TIMS (electronic/digital form submittals).	Not considered information collection under 5 CFR 1320.3(h)(1).		0
Subtotal			3,514 responses	3,514
			$162,750 non-hour cost burden.	
Disqualification				
101; 135; 136; Form BOEM–1832	Submit response and required information for INC, probation, or revocation of operating status. Notify when violations corrected.	2	94 submissions	188
	Request waiver of 14-day response time or reconsideration.	1	1	1
135; 136	Request reimbursement for services provided to BOEM representatives during reviews; comment.	1.5	2 requests	3
Subtotal			97 responses	192
Special Types of Approval				
125(c); 140	Request various oral approvals not specifically covered elsewhere in regulatory requirements.	1	100 requests	100
141; 101–199	Request approval to use new or alternative procedures; submit required information.	20	100 requests	2,000
142; 101–199	Request approval of departure from operating requirements not specifically covered elsewhere in regulatory requirements; submit required information.	2.5	100 requests	250
Subtotal			300 responses	2,350
Right-of-use and Easement				
160; 161; 123	OCS lessees: Apply for new or modified right-of-use and easement to construct and maintain off-lease platforms, artificial islands, and installations and other devices; include notifications and submitting required information.	9	26 applications	234
160(c)	Establish a Company File for qualification; submit updated information, submit qualifications for lessee/bidder, request exception.	Burden covered under 30 CFR 556 (1010–0006).		0
160; 165; 123	State lessees: Apply for new or modified right-of-use and easement to construct and maintain off-lease platforms, artificial islands, and installations and other devices; include pay.gov confirmation and notifications.	5	1 application	5
			$2,742 state lease fee × 1 = $2,742.	
166	State lessees: Furnish surety bond; additional security if required.	Burden covered under 30 CFR 556 (1010–0006).		0
Subtotal			27 responses	239
			$2,742 non-hour cost burden.	

BURDEN BREAKDOWN—Continued

Citation 30 CFR 550 subpart A and related forms/NTLs	Reporting or recordkeeping requirement	Non-hour cost burdens		
		Hour burden	Average number of annual responses	Annual burden hours
Primary Lease Requirements, Lease Term Extensions, and Lease Cancellations				
181(d); 182(b), 183(a)(b)	Request termination of suspension, cancellation of lease, lesser lease term (no requests in recent years for termination/cancellation of a lease; minimal burden).	20	1 request	20
182; 183, 185; 194	Various references to submitting new, revised, or modified exploration plan, development/production plan, or development operations coordination document, and related surveys/reports.	Burden covered under 30 CFR 550, subpart B (1010–0151).		0
184	Request compensation for lease cancellation mandated by the OCS Lands Act (no qualified lease cancellations in many years; minimal burden compared to benefit).	50	1 request	50
Subtotal			2 responses	70
Information and Reporting Requirements				
186(a)	Apply to receive administrative entitlements to eWell/TIMS system for electronic submissions.	Not considered IC under 5 CFR 1320.3(h)(1).		0
186; NTL	Submit information, reports, and copies as BOEM requires.	10	125	1,250
135; 136	Report apparent violations or non-compliance	1.5	2 reports	3
194; NTL	Report archaeological discoveries. Submit archaeological and follow-up reports and additional information.	2	6 reports	12
194; NTL	Request departures from conducting archaeological resources surveys and/or submitting reports in GOMR.	1	2 requests	2
194	Submit ancillary surveys/investigations reports, as required.	Burden covered under 30 CFR 550 Subpart B (1010–0151).		0
196	Submit data/information for G&G activity and request reimbursement.	Burden covered under 30 CFR 551 (1010–0048).		0
197(b)(2)	Demonstrate release of G&G data would unduly damage competitive position.	1	1	1
197	*Submit confidentiality agreement	1	1	1
Subtotal			137 responses	1,269
Recordkeeping				
135; 136	During reviews, make records available as requested by inspectors.	2	7 reviews	14
Subtotal			7 responses	14
Citation 30 CFR 550 subpart K and related forms	Well surveys and classifying reservoirs	Hour burden	Average number of annual responses	Annual burden hours
1153	Conduct static bottomhole pressure survey; submit Form BOEM–0140 (Bottomhole Pressure Survey Report) (within 60 days after survey).	14	1,161 surveys	16,254
1153(d)	Submit justification, information, and Form BOEM–0140, to request a departure from requirement to run a static bottomhole survey.	1	200 survey departures.	200

Citation 30 CFR 550 subpart K and related forms	Well surveys and classifying reservoirs	Hour burden	Average number of annual responses	Annual burden hours
1154; 1167	Submit request and supporting information to reclassify reservoir.	1	15 requests	15
1155; 1165(b); 1166; 1167	Submit Form BOEM–0127 (Sensitive Reservoir Information Report) and supporting information/revisions (within 45 days after certain events or at least annually). AK Region: submit BOEM–0127 and request MER.	3	2,012 forms	6,036
1153–1167	Request general departure or alternative compliance requests not specifically covered elsewhere in regulatory requirements.	1	2	2
1165	Submit proposed plan for enhanced recovery operations to BSEE.	Burden covered under BSEE 30 CFR 250 (1014–0019).		0
Subtotal			3,390 responses	22,507
Total Burden			7,567 responses	30,635
			$165,492 non-hour cost burdens.	

Estimated Reporting and Recordkeeping Non-Hour Cost Burden: We have identified two non-hour cost burdens. Section 550.143 requires a fee for a change in designation of operator ($175). Section 550.165 requires a State lessee applying for a right-of use and easement in the OCS to pay a cost recovery application fee ($2,742). These fees reflect the recent adjustment for inflation that became effective February 2, 2013 (78 FR 5836, 1/28/13).

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Before submitting an ICR to OMB, PRA section 3506(c)(2)(A) requires each agency ". . . to provide notice . . . and otherwise consult with members of the public and affected agencies concerning each proposed collection of information . . .". Agencies must specifically solicit comments on: (a) Whether or not the collection of information is necessary, including whether or not the information will have practical utility; (b) the accuracy of our burden estimates; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden on respondents.

Agencies must also estimate the non-hour cost burdens to respondents or recordkeepers resulting from the collection of information. Therefore, if you have costs to generate, maintain, and disclose this information, you should comment and provide your total capital and startup costs and annual operation, maintenance, and purchase of service costs. You should describe the methods you use to estimate major cost factors, including system and technology acquisition, expected useful life of capital equipment, discount rate(s), and the period over which you incur costs. Capital and startup costs include, among other items, computers and software you purchase to prepare for collecting information, monitoring, and record storage facilities. You should not include estimates for equipment or services purchased: (a) Before October 1, 1995; (b) to comply with requirements not associated with the information collection; (c) for reasons other than to provide information or keep records for the Government; or (d) as part of customary and usual business or private practices.

We will summarize written responses to this notice and address them in our submission for OMB approval. As a result of your comments, we will make any necessary adjustments to the burden in our submission to OMB.

Public Availability of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: September 12, 2016.

Deanna Meyer-Pietruszka,

Chief, Office of Policy, Regulations, and Analysis.

[FR Doc. 2016–22355 Filed 9–15–16; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[Docket No. BOEM–2016–0054]

Gulf of Mexico (GOM) Outer Continental Shelf (OCS) Central Planning Area (CPA) Oil and Gas Lease Sale 247; MMAA104000

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Notice of availability of a final supplemental environmental impact statement.

SUMMARY: BOEM is announcing the availability of a Final Supplemental Environmental Impact Statement (SEIS) for Gulf of Mexico (GOM) Outer Continental Shelf (OCS) Central Planning Area (CPA) Oil and Gas Lease Sale 247. The Final SEIS provides a discussion of potential significant impacts of the proposed action, provides an analysis of reasonable alternatives to the proposed action, and identifies the Bureau's preferred alternative.

The Final SEIS is available on the agency Web site at *http://www.boem.gov/nepaprocess/*. BOEM will primarily distribute digital copies of the Final SEIS on compact discs. You may request a paper copy or the location of a library with a digital copy of the

Final SEIS from BOEM, Gulf of Mexico OCS Region, Public Information Office (GM 250C), 1201 Elmwood Park Boulevard, Room 250, New Orleans, Louisiana 70123–2394 (1 800 200–GULF).

FOR FURTHER INFORMATION CONTACT: For more information on the CPA 247 Final SEIS, you may contact Mr. Gary D. Goeke, Bureau of Ocean Energy Management, Gulf of Mexico OCS Region, Office of Environment (GM 623E), 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394 or by email at *cpa247@boem.gov.* You may also contact Mr. Goeke by telephone at 504–736–3233.

Authority: This Notice of Availability of a Final Supplemental Environmental Impact Statement is in compliance with the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4231 *et seq.*), and is published pursuant to 40 CFR 1502.19.

Abigail Ross Hopper,

Director, Bureau of Ocean Energy Management.

[FR Doc. 2016–22212 Filed 9–15–16; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

Notice of Availability of the Proposed Notice of Sale for the Central Gulf of Mexico Planning Area Outer Continental Shelf Oil and Gas Lease Sale 247; MMAA104000

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Notice of availability of the Proposed Notice of Sale for Central Planning Area Lease Sale 247.

SUMMARY: BOEM announces the availability of the Proposed Notice of Sale (NOS) for the proposed Central Planning Area (CPA) Outer Continental Shelf (OCS) Oil and Gas Lease Sale 247 (CPA Sale 247). This Notice is published pursuant to 30 CFR 556.304(c) as a matter of information to the public. With regard to oil and gas leasing on the OCS, the Secretary of the Interior, pursuant to section 19 of the OCS Lands Act (43 U.S.C. 1331–1356a), provides affected states with the opportunity to review the Proposed NOS. The Proposed NOS sets forth the proposed terms and conditions of the sale, including minimum bids, royalty rates, and rental rates.

DATES: Affected states may comment on the size, timing, and location of proposed CPA Sale 247 within 60 days following receipt of the Proposed NOS. The Final NOS will be published in the **Federal Register** at least 30 days prior to the date of the bid opening. Bid opening is currently scheduled for March 22, 2017.

FOR FURTHER INFORMATION CONTACT: David Diamond, Chief, Leasing Division, *david.diamond@boem.gov.*

SUPPLEMENTARY INFORMATION: The Proposed NOS for CPA 247 and Proposed NOS package containing information essential to potential bidders may be obtained from the Public Information Unit, Gulf of Mexico Region, Bureau of Ocean Energy Management, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394. Telephone: (504) 736–2519. The Proposed NOS and Proposed NOS package are also available on BOEM's Web site at *http://www.boem.gov/Sale-247/.*

Dated: September 8, 2016.

Abigail Ross Hopper,

Director, Bureau of Ocean Energy Management.

[FR Doc. 2016–22211 Filed 9–15–16; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[MMAA104000]

Use of Outer Continental Shelf (OCS) Sand Resources for the Mississippi Coastal Improvements Program (MsCIP) Comprehensive Barrier Island Restoration in Hancock, Harrison, and Jackson Counties, Mississippi

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Notice of availability of the Record of Decision (ROD).

SUMMARY: BOEM is announcing the availability of the ROD that documents BOEM's decision to authorize the use of OCS sand resources by the U.S. Army Corps of Engineers (USACE) Mobile District in the MsCIP Comprehensive Barrier Island Restoration Project (Project) in Hancock, Harrison, and Jackson Counties, Mississippi. The ROD is available at BOEM's Web site at *http://www.boem.gov/Non-Energy-Minerals/Marine-Minerals-Program.aspx.* BOEM will enter into a Memorandum of Agreement (MOA) with the USACE and make available OCS sand for use in the MsCIP Comprehensive Barrier Island Restoration Project.

FOR FURTHER INFORMATION CONTACT: Terri L. Thomas, Bureau of Ocean Energy Management, Gulf of Mexico Region, Regional Supervisor, Office of Environment, 1201 Elmwood Park Blvd., New Orleans, LA 70123, (504) 736–2963, *terri.thomas@boem.gov.*

SUPPLEMENTARY INFORMATION: In 2009, the USACE Mobile District developed the MsCIP Comprehensive Plan (Plan) and Integrated Programmatic Environmental Impact Statement (2009 PEIS) to support the long-term recovery of Hancock, Harrison, and Jackson Counties, Mississippi from the severe erosion and storm damage caused by Hurricane Katrina and other storm events. The Plan includes a long-term strategy to make the Mississippi coast more resilient to damage from future storms and to compensate for historical navigational dredging and disposal activities that altered sediment availability and sediment transport along the barrier islands. The environmental impacts associated with the dredging of offshore sand resources and the placement of sand along East and West Ship Islands, and Cat Island located in Hancock, Harrison, and Jackson Counties, Mississippi, were evaluated in the MsCIP Comprehensive Barrier Island Restoration, Hancock, Harrison, and Jackson Counties, Mississippi, Final Supplemental Environmental Impact Statement (2016 SEIS), which tiers directly from the 2009 PEIS. The USACE's Mobile District served as the lead agency during the preparation of the 2009 PEIS and 2016 SEIS. BOEM served as a cooperating agency given its jurisdiction over OCS sand resources that were being considered for use in the Project. The borrow option selected by USACE and evaluated in the 2016 SEIS to implement the Plan includes 10 OCS locations with a total volume of 19.6 million cubic yards (MCY) of OCS sand. The USACE signed its own ROD in June 2016 and requested BOEM to authorize use of OCS sand.

BOEM and the USACE will enter into an MOA authorizing the use of up to 19.6 MCY of OCS sand from the identified OCS borrow areas. Under the OCS Lands Act (43 U.S.C. 1337(k)(2)), BOEM can convey, on a noncompetitive basis, the rights to use OCS sand, gravel, or shell resources for use in a program for shore protection, beach restoration, or coastal wetland restoration undertaken by a Federal, state, or local government agency (43 U.S.C. 1337(k)(2)).

As a cooperating agency, BOEM has independently reviewed and adopted the comprehensive analysis presented in the USACE's 2009 PEIS and 2016 SEIS (43 CFR 46.120). The 2009 PEIS and 2016 SEIS assessed the physical, biological, and social/human impacts of the proposed project and considered a range of alternatives, including a no-action alternative. The ROD discloses BOEM's decision, articulates the basis for the decision, summarizes the alternatives considered by BOEM, and identifies the environmentally preferable alternative and the mitigation measures BOEM is adopting. The USACE is committed to implementing the mitigation measures and monitoring requirements deemed practicable to avoid or minimize environmental harm. The mitigation measures and monitoring requirements are identified in BOEM's ROD and will be incorporated into the MOA between BOEM and the USACE. The Project will be constructed with the understanding that any proposed use of OCS sand in future coastal restoration activities will require an updated environmental analysis and new negotiated agreement.

Authority: This Notice of Availability is published pursuant to the regulations (40 CFR 1506.6) implementing the provisions of the NEPA of 1969 (42 U.S.C. 4321 *et seq.*).

Dated: September 12, 2015.

Abigail Ross Hopper,

Director, Bureau of Ocean Energy Management.

[FR Doc. 2016–22377 Filed 9–15–16; 8:45 am]

BILLING CODE 4310–MR–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–1019]

Certain Krill Oil Products and Krill Meal for Production of Krill Oil Products; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on August 12, 2016, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Aker BioMarine Antarctic AS of Norway and Aker BioMarine Manufacturing, LLC of Houston, Texas. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain krill oil products and krill meal for production of krill oil products by reason of infringement of certain claims of U.S. Patent No. 9,028,877 ("the '877 patent"); U.S. Patent No. 9,078,905 ("the '905 patent"); U.S. Patent No. 9,072,752 ("the '752 patent"); U.S. Patent No. 9,320,765 ("the '765 patent"); and U.S. Patent No. 9,375,453 ("the '453 patent"). The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order, and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Docket Services, U.S. International Trade Commission, telephone (202) 205–1802.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2016).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on September 12, 2016, *Ordered That—*

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain krill oil products and krill meal for production of krill oil products by reason of infringement of one or more of claims 1–4, 7–9, 11–13, and 16–18 of the '877 patent; claims 1–4, 6–7, 9–11, 12, and 15–19 of the '905 patent; claims 1, 7, and 11–13 of the '752 patent; claims 1–5, 7, 9–12, 14–15, 19–21, 23, 25–29, 31, 33–36, 38–39, 43–45, and 47 of the '765 patent; and claims 1, 5–10, 12, 14–17, 19–20, 24–26, 28, 30–32, 33–36, 39–43, 46–49, 51–52, 56–58, and 60 of the '453 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

Aker BioMarine Antarctic AS Oksenøyveien, 10 P.O. Box 496. N–1327, Lysaker, Norway

Aker BioMarine Manufacturing, LLC, 4494 Campbell Rd, Houston, TX 77041

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Olympic Holding AS, Fosnavåg Brygge Holmsildgata 12, Fosnavåg, Norway

Rimfrost AS, Vågsplassen, 6090, Fosnavåg, Norway

Emerald Fisheries AS, Fosnavåg Brygge, 6090 Fosnavåg, Norway

Avoca Inc., 841 Avoca Farm Rd., Merry Hill, NC 27957

Rimfrost USA, LLC, 841 Avoca Farm Rd., Merry Hill, NC 27957

Rimfrost New Zealand Limited, 20 Oxford Street Richmond, Nelson, New Zealand 7020

Bioriginal Food & Science Corp., 102 Melville Street,, Saskatoon, Saskatchewan, Canada S7J 0R1

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the

Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: September 12, 2016

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–22296 Filed 9–15–16; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–540, 542–544 and 731–TA–1283, 1285, 1287, and 1289–1290 (Final)]

Cold-Rolled Steel Flat Products From Brazil, India, Korea, Russia, and the United Kingdom; Determinations

On the basis of the record[1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is materially injured by reason of imports of cold-rolled steel flat products from Brazil, India, Korea, and the United Kingdom, provided for in subheadings 7209.15, 7209.16, 7209.17, 7209.18, 7209.25, 7209.26, 7209.27, 7209.28, 7209.90, 7210.70, 7211.23, 7211.29, 7211.90, 7212.40, 7225.50, 7225.99, and 7226.92 of the Harmonized Tariff Schedule of the United States, that have been found by the Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV''), and to be subsidized by the governments of Brazil and Korea. The Commission further determines that an industry in the United States is threatened with material injury by reason of imports of cold-rolled steel flat products that have been found by Commerce to be subsidized by the government of India.[2] The Commission also determines that imports of cold-rolled steel flat products from Russia that are sold in the United States at LTFV and subsidized by the government of Russia are negligible.

Background

The Commission, pursuant to sections 705(b) and 735(b) of the Act (19 U.S.C. 1671d(b) and 19 U.S.C. 1673d(b)), instituted these investigations effective July 28, 2015, following receipt of a petition filed with the Commission and Commerce by AK Steel Corporation (West Chester, Ohio), ArcelorMittal USA LLC (Chicago, Illinois), Nucor Corporation (Charlotte, North Carolina), Steel Dynamics, Inc. (Fort Wayne, Indiana), and United States Steel Corporation (Pittsburgh, Pennsylvania). The final phase of the investigations was scheduled by the Commission following notification of preliminary determinations by Commerce that imports of cold-rolled steel flat products from Brazil, India, Korea, and Russia were subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)) and imports of cold-rolled steel flat products imported from Brazil, India, Korea, Russia, and the United Kingdom were dumped within the meaning of 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the final phase of the Commission's investigations[3] and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on March 23, 2016 (81 FR 15559). The hearing was held in Washington, DC, on May 24, 2016, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to sections 705(b) and 735(b) of the Act (19 U.S.C. 1671d(b) and 19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on September 12, 2016. The views of the Commission are contained in USITC Publication 4637 (September 2016), entitled *Cold-Rolled Steel Flat Products from Brazil, India, Korea, Russia, and the United Kingdom: Investigation Nos. 701–TA–540 and 542–544 and 731–TA–1283, 1285, 1287, and 1289–1290 (Final).*

By order of the Commission.

Issued: September 12, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–22297 Filed 9–15–16; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Securing Financial Obligations Under the Longshore and Harbor Workers' Compensation Act and its Extensions

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Office of Workers' Compensation Programs (OWCP) sponsored information collection request (ICR) titled, ''Securing Financial Obligations Under the Longshore and Harbor Workers' Compensation Act and its Extensions,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before October 17, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201606-1240-002* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OWCP, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at

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[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Commissioner F. Scott Kieff dissenting. Commissioner Kieff determines that imports subsidized by the government of India are negligible.

[3] The Commission also scheduled a final-phase countervailing duty investigation concerning cold-rolled flat products from Korea, although Commerce preliminarily determined that *de minimis* countervailable subsidies were being provided to producers/exporters of certain cold-rolled steel flat products from Korea.

202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Securing Financial Obligations Under the Longshore and Harbor Workers' Compensation Act (LHWCA) and its Extensions information collection. The LHWCA requires a covered employer to secure the payment of compensation under the Act and its extensions by purchasing insurance from a carrier authorized by the Secretary of Labor to write insurance under the LHWCA, or by becoming an authorized self-insured employer. Each authorized insurance carrier or carrier seeking authorization is required to establish annually that its LHWCA obligations are fully secured through an applicable state guaranty or analogous fund, a deposit of security with the Division of Longshore and Harbor Workers' Compensation (DLHWC), or a combination of both. Similarly, each authorized self-insurer or employer seeking authorization is required fully to secure its LHWCA obligations by depositing security with the DLHWC. These requirements are designed to assure the prompt and continued payment of compensation and other benefits by the responsible carrier or self-insurer to injured workers and their survivors. Forms associated with this information collection [Forms LS–275 IC, Agreement and Undertaking (Insurance Carrier); LS–275 SI, Agreement and Undertaking (Self-Insured Employer); and LS–276, Application for Security Deposit Determination] obtain information used to determine appropriate security deposit amounts and to insure compliance with the security deposit requirements. LHWCA section 32 authorizes this information collection. *See* 33 U.S.C. 932.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1240–0005.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on October 31, 2016. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on June 15, 2016 (81 FR 39066).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1240–0005. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: DOL–OWCP.

Title of Collection: Securing Financial Obligations Under the Longshore and Harbor Workers' Compensation Act and its Extensions.

OMB Control Number: 1240–0005.

Affected Public: Private Sector—businesses or other for-profits and not-for-profit institutions.

Total Estimated Number of Respondents: 569.

Total Estimated Number of Responses: 686.

Total Estimated Annual Time Burden: 472 hours.

Total Estimated Annual Other Costs Burden: $343.

Dated: September 9, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–22308 Filed 9–15–16; 8:45 am]

BILLING CODE 4510–CF–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Disability Employment Initiative Evaluation

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Office of Disability Employment Policy (ODEP) sponsored information collection request (ICR) proposal titled, "Disability Employment Initiative Evaluation," to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995. Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before October 17, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201609-1230-001* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ODEP, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–

4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This ICR seeks PRA authority for the information collection requirements to conduct an evaluation of the Disability Employment Initiative (DEI). The DEI was designed to improve educational, training and employment opportunities and outcomes of youth and adults with disabilities by refining and expanding already identified successful public workforce strategies; improving coordination and collaboration among employment and training and asset development programs implemented at state and local levels; and build effective community partnerships that leverage public and private resources better to serve individuals with disabilities and improve employment outcomes. The study will use two distinct quasi-experimental design study designs to determine the impact of DEI interventions on participant outcomes. Information will be collected through annual site visits, a participant tracking system, and a survey.

This proposed information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. For additional information, see the related notices published in the **Federal Register** on January 12, 2016 (81 FR 1446) and May 26, 2016 (81 FR 36350).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB ICR Reference Number 201609–1230–001. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: DOL–ODEP.

Title of Collection: Disability Employment Initiative Evaluation.

OMB ICR Reference Number: 201609–1230–001.

Affected Public: Individuals or Households; State, Local, and Tribal Governments; Private Sector—businesses or other for-profits and not-for-profit institutions.

Total Estimated Number of Respondents: 5,655.

Total Estimated Number of Responses: 5,655.

Total Estimated Annual Time Burden: 819 hours.

Total Estimated Annual Other Costs Burden: $0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: September 12, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–22307 Filed 9–15–16; 8:45 am]

BILLING CODE 4510–FK–P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Intent To Renew the Bureau of Labor Statistics Technical Advisory Committee

The Secretary of Labor is announcing the intent to renew a Federal Advisory Committee. In accordance with the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, the Secretary of Labor has determined that the renewal of the Bureau of Labor Statistics Technical Advisory Committee (the "Committee") is in the public interest in connection with the performance of duties imposed upon the Commissioner of Labor Statistics by 29 U.S.C. 1 and 2. This determination follows consultation with the Committee Management Secretariat, General Services Administration.

The Committee presents advice and makes recommendations to the Bureau of Labor Statistics (BLS) on technical aspects of the collection and formulation of economic measures.

The Committee functions solely as an advisory body to the BLS, on technical topics selected by the BLS. Important aspects of the Committee's responsibilities include, but are not limited to:

a. Provide comments on papers and presentations developed by BLS research and program staff. The comments will address the technical soundness of the research and whether it reflects best practices in the relevant fields.

b. Recommend that BLS conduct research projects to address technical problems with BLS statistics that have been identified in the academic literature.

c. Participate in discussions of areas where the types or coverage of economic statistics could be expanded or improved and areas where statistics are no longer relevant.

The Committee reports to the Commissioner of Labor Statistics, Bureau of Labor Statistics, U.S. Department of Labor.

The Committee consists of approximately sixteen members who serve as Special Government Employees. Members are appointed by the BLS and are approved by the Secretary of Labor. Committee members are economists, statisticians, and behavioral scientists and are chosen to achieve a balanced membership across those disciplines. They are prominent experts in their fields and recognized for their professional achievements and objectivity.

The Committee will function solely as an advisory body, in compliance with the provisions of the Federal Advisory Committee Act. The Charter will be filed under the Federal Advisory Committee Act.

FOR FURTHER INFORMATION CONTACT: Lisa Fieldhouse, Office of the Commissioner, Bureau of Labor Statistics, telephone: 202–691–5025, email: *fieldhouse.lisa@bls.gov.*

Signed at Washington, DC, this 12th day of September 2016.

Kimberley D. Hill,

Chief, Division of Management Systems, Bureau of Labor Statistics.

[FR Doc. 2016–22309 Filed 9–15–16; 8:45 am]

BILLING CODE 4510–24–P

LEGAL SERVICES CORPORATION

Sunshine Act Meeting

DATE AND TIME: The Legal Services Corporation's Board of Directors will meet telephonically on September 21, 2016. The meeting will commence at 4:00 p.m., EDT, and will continue until the conclusion of the Committee's agenda.

LOCATION: John N. Erlenborn Conference Room, Legal Services Corporation Headquarters, 3333 K Street NW., Washington, DC 20007.

PUBLIC OBSERVATION: Members of the public who are unable to attend in person but wish to listen to the public proceedings may do so by following the telephone call-in directions provided below.

CALL-IN DIRECTIONS FOR OPEN SESSIONS:

- Call toll-free number: 1–866–451–4981;
- When prompted, enter the following numeric pass code: 5907707348
- When connected to the call, please immediately "MUTE" your telephone.

Members of the public are asked to keep their telephones muted to eliminate background noises. To avoid disrupting the meeting, please refrain from placing the call on hold if doing so will trigger recorded music or other sound. From time to time, the Chair may solicit comments from the public.

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

1. Approval of agenda
2. Approval of the Board's Open Session meeting of July 17 and July 19, 2016
3. Consider and act on revisions to the LSC 2017—2020 Strategic Plan
4. Public comment
5. Consider and act on other business
6. Consider and act on adjournment of meeting.

CONTACT PERSON FOR INFORMATION: Katherine Ward, Executive Assistant to the Vice President & General Counsel, at (202) 295–1500. Questions may be sent by electronic mail to *FR_NOTICE_QUESTIONS@lsc.gov.*

ACCESSIBILITY: LSC complies with the Americans with Disabilities Act and Section 504 of the 1973 Rehabilitation Act. Upon request, meeting notices and materials will be made available in alternative formats to accommodate individuals with disabilities. Individuals needing other accommodations due to disability in order to attend the meeting in person or telephonically should contact Katherine Ward, at (202) 295–1500 or *FR_NOTICE_QUESTIONS@lsc.gov,* at least 2 business days in advance of the meeting. If a request is made without advance notice, LSC will make every effort to accommodate the request but cannot guarantee that all requests can be fulfilled.

Dated: September 14, 2016.

Katherine Ward,

Executive Assistant to the Vice President for Legal Affairs and General Counsel.

[FR Doc. 2016–22489 Filed 9–14–16; 4:15 pm]

BILLING CODE 7050–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Intent To Extend an Information Collection

AGENCY: National Science Foundation.

ACTION: Notice and Request for Comments.

SUMMARY: The National Science Foundation (NSF) is announcing plans to request renewal of the Survey of Earned Doctorates (OMB No. 3145–0019). In accordance with the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting that OMB approve clearance of this collection for three years.

DATES: Written comments on this notice must be received by November 14, 2016, to be assured of consideration. Comments received after that date will be considered to the extent practicable.

FOR ADDITIONAL INFORMATION OR COMMENTS: Contact Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Boulevard, Suite 1265, Arlington, Virginia 22230; telephone (703) 292–7556; or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays). You also may obtain a copy of the data collection instrument and instructions from Ms. Plimpton.

SUPPLEMENTARY INFORMATION:

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the NSF, including whether the information shall have practical utility; (b) the accuracy of the NSF's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, use, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title of Collection: Survey of Earned Doctorates.

OMB Control Number: 3145–0019.

Expiration Date of Current Approval: May 31, 2018.

Type of Request: Intent to seek approval to extend an information collection for three years.

1. *Abstract:* Established within the National Science Foundation by the America COMPETES Reauthorization Act of 2010 § 505, codified in the National Science Foundation Act of 1950, as amended, the National Center for Science and Engineering Statistics (NCSES) serves as a central Federal clearinghouse for the collection, interpretation, analysis, and dissemination of objective data on science, engineering, technology, and research and development for use by practitioners, researchers, policymakers, and the public. The Survey of Earned Doctorates (SED) is part of an integrated survey system that collects data on individuals in an effort to provide information on science and engineering education and careers in the United States.

The SED has been conducted annually since 1958 and is jointly sponsored by the National Science Foundation, National Institutes of Health, U.S. Department of Education, and National Endowment for the Humanities in order to avoid duplication. It is an accurate, timely source of information on one of our Nation's most important resources—highly educated individuals. Data are obtained via Web survey or paper questionnaire from each person earning a research doctorate at the time they receive the degree. Data are collected on their field of specialty, educational background, sources of support in graduate school, debt level, postgraduation plans, and demographic characteristics.

The Federal government, universities, researchers, and others use the information extensively. The National Science Foundation, as the lead agency, publishes statistics from the survey in several reports, but primarily in the annual publication series *Doctorate Recipients from U.S. Universities.* These reports are available on the NSF Web site.

The survey will be collected in conformance with the Privacy Act of 1974. Responses from individuals are voluntary. NSF will ensure that all individually identifiable information collected will be kept strictly confidential and will be used only for research or statistical purposes.

2. *Use of the Information:* Results from the SED are used to assess characteristics of the doctorate population and trends in doctoral education and degrees by researchers, policy makers, universities, and government agencies. Data from the survey are published annually on the NCSES Web site in a publication series reporting on all fields of study, titled *Doctorate Recipients from U.S. Universities.* Information from the SED is also included in other series available online: *Science and Engineering Degrees; Science and Engineering Degrees, by Race/Ethnicity of Recipients; Science and Engineering Indicators;* and *Women, Minorities, and Persons with Disabilities in Science and Engineering.* In addition, access to tabular data from selected variables is available through WebCASPAR, an online table-generating tool on the NCSES Web site.

3. *Expected Respondents:* The SED is a census of all individuals receiving a research doctorate from an accredited U.S. academic institution in the academic year beginning 1 July and ending 30 June of the subsequent year. As such, the population for the 2018 SED consists of all individuals receiving a research doctorate in the 12-month period beginning 1 July 2017 and ending 30 June 2018. Likewise, the population for the 2019 SED consists of all individuals receiving a research doctorate in the 12-month period beginning 1 July 2018 and ending 30 June 2019. A research doctorate is a doctoral degree that (1) requires completion of an original intellectual contribution in the form of a dissertation or an equivalent culminating project (*e.g.,* musical composition) and (2) is not primarily intended as a degree for the practice of a profession. The most common research doctorate degree is the Ph.D. Recipients of professional doctoral degrees only, such as MD, DDS, JD, DPharm, and PsyD, are not included in the SED. The 2018 and 2019 SED are expected to include about 580 separately reporting doctoral programs from among approximately 455 eligible research doctorate-granting institutions.

4. *Estimate of Burden:* A total response rate of 90% of the 55,006 persons who earned a research doctorate from a U.S. institution was obtained in academic year 2015. This level of response rate has been consistent for several years. Based on the historical trend, in 2018 approximately 58,000 individuals are expected to receive research doctorates from U.S. institutions. Using the past response rate, the number of SED respondents in 2018 is estimated to be 52,200 (58,000 doctorate recipients × 0.90 response rate). Similarly, the number of individuals expected to earn research doctorates in 2019 is estimated to be about 59,000; hence, the number of respondents in 2019 is estimated to be 53,100 (59,000 × 0.90).

Based on the average Web survey completion time for the 2017 SED (19 minutes) and the extension of a few questions to an additional subset of respondents, NSF estimates that, on average, 21 minutes per respondent will be required to complete the 2018 or 2019 SED questionnaire. The annual respondent burden for completing the SED is therefore estimated at 18,270 hours in 2018 (52,200 respondents × 21 minutes) and 18,585 hours in 2019 (based on 53,100 respondents).

In addition to the actual questionnaire, the SED requires the collection of administrative data from participating academic institutions. The Institutional Coordinator at the institution helps distribute the Web survey link (and paper surveys when necessary), track survey completions, and submit information to the SED survey contractor. Based on focus groups conducted with Institutional Coordinators, it is estimated that the SED demands no more than 1% of the Institutional Coordinator's time over the course of a year, which computes to 20 hours per year per Institutional Coordinator (40 hours per week × 50 weeks per year × .01). With about 580 programs expected to participate in the SED in 2018 and 2019, the estimated annual burden to Institutional Coordinators of administering the SED is 11,600 hours.

Therefore, the total annual information burden for the SED is estimated to be 29,870 hours in 2018 (18,270 + 11,600) and 30,185 hours in 2019 (18,585 + 11,600). This is higher than the last annual estimate approved by OMB due to the increased number of respondents (doctorate recipients) and the increased number of survey questions being asked of each respondent.

Authority: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (Pub. L. 104–13)

Dated: September 13, 2016.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2016–22285 Filed 9–15–16; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–247 and 50–286; NRC–2016–0197]

Entergy Nuclear Operations, Inc., Indian Point Nuclear Generating Unit Nos. 2 and 3

AGENCY: Nuclear Regulatory Commission.

ACTION: 10 CFR 2.206 request; receipt.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is giving notice that by petition dated June 30, 2016, Mr. David A. Lochbaum of the Union of Concerned Scientists (the petitioner) requested that the NRC take action with regard to Indian Point Nuclear Generating Unit Nos. 2 and 3. The petitioner's requests are included in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: Please refer to Docket ID NRC–2016–0197 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0197. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.*
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

SUPPLEMENTARY INFORMATION: On June 30, 2016, the petitioner requested that the NRC take action with regard to Indian Point Nuclear Generating Unit Nos. 2 and 3 (ADAMS Accession No. ML16187A186). The petitioner requested that the NRC take the following enforcement actions:

1. Issue an Order requiring the Indian Point licensee to inspect the reactor vessel baffle-former bolts and to install the downflow to upflow modification on Unit 2 during its next refueling outage;

2. Issue a Demand for Information requiring the Indian Point licensee to submit an operability determination to the agency regarding continued operation of Unit 3 until its reactor vessel baffle-former bolts can be inspected per Material Reliability Project–227–A; and

3. Issue a Demand for Information requiring the Indian Point licensee to submit an evaluation of the performance, role and operating experience of the metal impact monitoring system in detecting and responding to indications of loose parts (such as broken baffle bolts) within the reactor coolant system.

As the basis for this request, the petitioner cited Licensee Event Report 2016–004–00 ''Unanalyzed Condition due to Degraded Reactor Baffle-Former Bolts,'' submitted by the licensee on May 31, 2016 (ADAMS Accession No. ML16159A219) that describes an event where there was an unanalyzed condition due to degraded reactor vessel baffle-former bolts at Indian Point Unit 2, which is reportable under § 50.73(a)(2)(ii)(B) of title 10 of the *Code of Federal Regulations* (10 CFR). Furthermore, the petitioner states that (1) an order is the proper means for ensuring that the bolts are inspected and that the downflow to upflow modification is installed during the next refueling outage at Indian Point Unit 2; (2) Indian Point Unit 3 is potentially operating with degraded baffle-former bolts and an operability determination is the mechanism established by the NRC to properly evaluate situations such as this; and (3) the metal impact monitoring system as described in the Updated Final Safety Analysis Report, has the potential to act as an alternate monitoring system to identify degraded baffle-former bolts, yet neither the NRC nor the licensee have referred to this system in publicly available documents relating to this issue.

The request is being treated pursuant to Section 2.206 of Title 10 of the *Code of Federal Regulations* (10 CFR) of the Commission's regulations. The request has been referred to the Director of the Office of Nuclear Reactor Regulation. As provided by 10 CFR 2.206, appropriate action will be taken on this petition within a reasonable time. The petitioner met with the Petition Review Board on July 28, 2016, to discuss the petition; the transcript of that meeting is an additional supplement to the petition (ADAMS Accession No. ML16215A391).

Dated at Rockville, Maryland, this 7th day of September 2016.

For the Nuclear Regulatory Commission.

William M. Dean,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–22380 Filed 9–15–16; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: 3206–0208, Representative Payee Survey, RI 38–115

AGENCY: U.S. Office of Personnel Management.

ACTION: 60-Day Notice and request for comments.

SUMMARY: The Retirement Services, Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on an extension, without change, of a currently approved information collection request (ICR) 3206–0208, Representative Payee Survey. As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection.

DATES: Comments are encouraged and will be accepted until November 15, 2016. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the U.S. Office of Personnel Management, Retirement Services, 1900 E Street NW., Room 2347E, Washington, DC 20415, Attention: Alberta Butler, or sent by email to *Alberta.Butler@opm.gov.*

FOR FURTHER INFORMATION CONTACT: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW., Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent by email to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910.

SUPPLEMENTARY INFORMATION: The Representative Payee Survey is used to collect information about how the benefits paid to a representative payee have been used or conserved for the benefit of the incompetent annuitant. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of OPM, including whether the information will have practical utility;
2. Evaluate the accuracy of OPM's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Representative Payee Survey.

OMB Number: 3206–0208.

Frequency: Annually.

Affected Public: Individuals or Households.

Number of Respondents: 11,000.

Estimated Time per Respondent: 20 minutes.

Total Burden Hours: 3,667.

U.S. Office of Personnel Management.

Beth F. Cobert,

Acting Director.

[FR Doc. 2016–22329 Filed 9–15–16; 8:45 am]

BILLING CODE 6325–38–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78817; File No. SR–NYSEMKT–2016–84]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 67—Equities To Modify Certain Data Collection Requirements of the Regulation NMS Plan To Implement a Tick Size Pilot Program

September 12, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on August 29, 2016, NYSE MKT LLC (the "Exchange" or "NYSE MKT") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

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[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 67—Equities to modify certain data collection requirements of the Regulation NMS Plan to Implement a Tick Size Pilot Program. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

On August 25, 2014, NYSE MKT, and several other self-regulatory organizations (the "Participants") filed with the Commission, pursuant to Section 11A of the Act[4] and Rule 608 of Regulation NMS thereunder,[5] the Plan to Implement a Tick Size Pilot Program (the "Plan").[6] The Participants filed the Plan to comply with an order issued by the Commission on June 24, 2014.[7] The Plan was published for comment in the **Federal Register** on November 7, 2014, and approved by the Commission, as modified, on May 6, 2015.[8]

The Plan is designed to allow the Commission, market participants, and the public to study and assess the impact of increment conventions on the liquidity and trading of the common stock of small-capitalization companies. Each Participant is required to comply, and to enforce compliance by its member organizations, as applicable, with the provisions of the Plan.

The Plan provides for the creation of a group of Pilot Securities, which shall be placed in a control group and three separate test groups, with each subject to varying quoting and trading increments. Pilot Securities in the control group will be quoted at the current tick size increment of $0.01 per share and will trade at the currently permitted increments. Pilot Securities in the first test group will be quoted in $0.05 minimum increments but will continue to trade at any price increment that is currently permitted.[9] Pilot Securities in the second test group ("Test Group Two") will be quoted in $0.05 minimum increments and will trade at $0.05 minimum increments subject to a midpoint exception, a retail investor order exception, and a negotiated trade exception.[10] Pilot Securities in the third test group ("Test Group Three") will be subject to the same quoting and trading increments as Test Group Two, and also will be subject to the "Trade-at" requirement to prevent price matching by a market participant that is not displaying at the price of a Trading Center's "Best Protected Bid" or "Best Protected Offer," unless an enumerated exception applies.[11] In addition to the exceptions provided under Test Group Two, an exception for Block Size orders and exceptions that mirror those under Rule 611 of Regulation NMS[12] will apply to the Trade-at requirement.

The Plan also requires a Trading Center[13] or a Market Maker[14] to collect and transmit certain data to its designated examining authority ("DEA"), and requires DEAs to transmit this data to the Commission. Participants that operate a Trading Center also are required under the Plan to collect certain data, which is then transmitted directly to the Commission. With respect to Trading Centers, Appendix B.I to the Plan (Market Quality Statistics) requires a Trading Center to submit to the Participant that is its DEA a variety of market quality statistics. Appendix B.II to the Plan (Market and Marketable Limit Order Data) requires a Trading Center to submit information to its DEA relating to market orders and marketable limit orders, including the time of order receipt, order type, the order size, and the National Best Bid and National Best Offer quoted price.

With respect to Market Makers, Appendix B.III requires a Participant that is a national securities exchange to collect daily Market Maker Registration statistics. Appendix B.IV requires a Participant to collect data related to Market Maker participation with respect to each Market Maker engaging in trading activity on a Trading Center operated by the Participant. Appendix C.I requires a Participant to collect data related to Market Maker profitability from each Market Maker for which it is the DEA. Appendix C.II requires the Participant, as DEA, to aggregate the Appendix C.I data, and to transmit this data to the Commission.

The Commission approved the Pilot on a two-year basis, with implementation to begin no later than May 6, 2016.[15] On November 6, 2015, the SEC exempted the Participants from implementing the pilot until October 3, 2016.[16] As set forth in Appendices B and C to the Plan, data that is reported pursuant to the appendices shall be provided for dates starting six months prior to the Pilot Period through six months after the end of the Pilot Period. Under the revised Pilot implementation date, the Pre-Pilot data collection period commenced on April 4, 2016.

On March 29, 2016, NYSE MKT filed with the Commission a proposed rule change to adopt NYSE MKT Rule 67(b)—Equities to implement the data collection requirements of the Plan.[17]

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[4] 15 U.S.C. 78k–1.

[5] 17 CFR 242.608.

[6] *See* Letter from Brendon J. Weiss, Vice President, Intercontinental Exchange, Inc., to Secretary, Commission, dated August 25, 2014.

[7] *See* Securities Exchange Act Release No. 72460 (June 24, 2014), 79 FR 36840 (June 30, 2014).

[8] *See* Securities Exchange Act Release No. 74892 (May 6, 2015), 80 FR 27513 (May 13, 2015) ("Approval Order").

[9] *See* Section VI(B) of the Plan.

[10] *See* Section VI(C) of the Plan.

[11] *See* Section VI(D) of the Plan.

[12] 17 CFR 242.611.

[13] The Plan incorporates the definition of a "Trading Center" from Rule 600(b)(78) of Regulation NMS. Regulation NMS defines a "Trading Center" as "a national securities exchange or national securities association that operates an SRO trading facility, an alternative trading system, an exchange market maker, an OTC market maker, or any other broker or dealer that executes orders internally by trading as principal or crossing orders as agent." *See* 17 CFR 242.600(b).

[14] The Plan defines a Market Maker as "a dealer registered with any self-regulatory organization, in accordance with the rules thereof, as (i) a market maker or (ii) a liquidity provider with an obligation to maintain continuous, two-sided trading interest."

[15] *See* Approval Order at 27533 and 27545.

[16] *See* Securities Exchange Act Release No. 76382 (November 6, 2015), 80 FR 70284 (November 13, 2015) (File No. 4–657).

[17] *See* Securities Exchange Act Release No. 77478 (March 30, 2016), 81 FR 19665 (April 5, 2016) (Immediate Effectiveness of Proposed Rule Change

On December 9, 2015, NYSE MKT submitted an exemptive request to the Commission, seeking an exemption from certain data collection and reporting requirements set forth in the Plan.[18] On April 4, 2016, the Commission granted exemptive relief from complying with certain data collection and reporting requirements in the Plan.[19]

NYSE MKT now proposes to further amend Rule 67—Equities to modify additional data collection and reporting requirements. First, Appendix B.I.a(21) through B.I.a(27) currently requires that Trading Centers report the cumulative number of shares of cancelled orders during a specified duration of time after receipt of the order that was cancelled. NYSE MKT and the other Participants believe that, for purposes of reporting cancelled orders, it is appropriate to categorize unexecuted Immediate or Cancel orders separately as one bucket irrespective of the duration of time after order receipt, *i.e.,* without a time increment, to better differentiate orders cancelled subsequent to entry from those where the customer's intent prior to order entry was to cancel the order if no execution could be immediately obtained. NYSE MKT, therefore, proposes to modify Supplementary Material .30 to provide that unexecuted Immediate or Cancel orders shall be categorized separately for purposes of Appendix B.I.a(21) through B.I.a(27).

The second change relates to the reporting of daily market quality statistics pursuant to Appendix B.I. Currently, Appendix B.I sets forth categories of orders, including market orders, marketable limit orders, and inside-the-quote resting limit orders, for which daily market quality statistics must be reported. NYSE MKT and the other Participants have determined that it is appropriate to include an order type for limit orders priced more than $0.10 away from the NBBO for purposes of Appendix B reporting. NYSE MKT therefore proposes to amend Supplementary Material .50 to provide that limit orders priced more than $0.10 away from the NBBO shall be included as an order type for purposes of Appendix B reporting, and shall be assigned the number (22). These orders are not currently required to be reported pursuant to Appendix B, and NYSE MKT and the other Participants believe that requiring the reporting of such orders will produce a more comprehensive data set.

The third change relates to the reporting of market quality statistics pursuant to Appendix B.I for a variety of order types, including inside-the-quote resting limit orders (12), at-the-quote resting limit orders (13), and near-the-quote resting limit orders (within $0.10 of the NBBO) (14). NYSE MKT and the other Participants believe that it is appropriate to require Trading Centers to report all orders that fall within these categories, and not just those orders that are "resting." NYSE MKT, therefore, proposes to amend Supplementary Material .50 to make this change.

In the fourth change, NYSE MKT proposes to add new Supplementary Material .100 to modify the manner in which market maker participation statistics are calculated. Currently, Appendix B.IV provides that market maker participation statistics shall be calculated based on share participation, trade participation, cross-quote share (trade) participation, inside-the-quote share (trade) participation, at-the-quote share (trade) participation, and outside-the-quote share (trade) participation. NYSE MKT and the other Participants have determined that it is appropriate to add the count of the number of Market Makers used in the calculation of share (trade) participation to each category. NYSE MKT is therefore proposing this change as part of Supplementary Material .100. In addition, Appendix B.IV(b) and (c) currently require that, when aggregating across Market Makers, share participation and trade participation shall be calculated using the share-weighted average and trade-weighted average, respectively. NYSE MKT and the other Participants believe that it is more appropriate to calculate share and trade participation by providing the total count of shares or trades, as applicable, rather than weighted averages, and NYSE MKT is therefore proposing this change as part of Supplementary Material .100.

The fifth change relates to the NBBO that a Trading Center is required to use when performing certain quote-related calculations. When calculating cross-quote share (trade) participation pursuant to Appendix B.IV(d) and inside-the-quote share (trade) participation pursuant to Appendix B.IV(e), the Plan requires the Trading Center to utilize the NBBO at the time of the trade for both share and trade participation calculations. When calculating at-the-quote share (trade) participation and outside-the-quote share (trade) participation pursuant to Appendix B.IV(f) and (g), the Plan allows the Trading Center to utilize the National Best Bid or National Best Offer (NBBO) at the time of or immediately before the trade for both share and trade participation calculations. NYSE MKT and the other Participants believe that it is appropriate to calculate all quote participation (cross-quote share (trade) participation, inside-the-quote share (trade) participation, at-the-quote share (trade) participation and outside-the-quote share (trade) participation) solely by reference to the NBBO in effect immediately prior to the trade. NYSE MKT therefore proposes to make this change as part of Supplementary Material .100.

Finally, NYSE MKT proposes to change the end date until which the Pre-Pilot Data Collection Securities shall be used to fulfill the Plan's data collection requirements. Currently, Supplementary Material .90 provides that Pre-Pilot Data Collection Securities are the securities designated by the Participants for purposes of the data collection requirements described in Items I, II and IV of Appendix B and Item I of Appendix C to the Plan for the period beginning six months prior to the Pilot Period and ending on the trading day immediately preceding the Pilot Period. NYSE MKT and the other Participants believe that it is appropriate to use the Pilot Securities to satisfy the Plan's data collection requirements prior to the commencement of the Pilot. Accordingly, NYSE MKT is revising Supplementary Material .90 to provide that the Pre-Pilot Data Collection Securities shall be used to satisfy the Plan's data collection requirements through thirty-one days prior to the Pilot Period, after which time the Pilot Securities shall be used for purposes of the data collection requirements.[20]

Adopting Requirements for the Collection and Transmission of Data Pursuant to Appendices B and C of the Regulation NMS Plan to Implement a Tick Size Pilot Program) (SR–NYSEMKT–2016–40).

NYSE MKT also submitted a proposed rule change to implement the quoting and trading requirements of the Plan. *See* Securities Exchange Act Release No. 77949 (May 31, 2016), 81 FR 36367 (June 6, 2016) (Immediate Effectiveness of Proposed Rule Change Implementing the Quoting and Trading Provisions of the Plan to Implement a Tick Size Pilot Program) (SR–NYSEMKT–2016–56).

[18] *See* Letter from Marcia E. Asquith, Senior Vice President and Corporate Secretary, FINRA, to Robert W. Errett, Deputy Secretary, Commission, dated December 9, 2015 ("Exemptive Request").

[19] *See* letter from John C. Roeser, Associate Director, Division of Trading and Markets, Commission, to Sherry Sandler, Associate General Counsel, NYSE MKT, dated April 4, 2016.

[20] After regular trading hours on September 2, 2016, the national securities exchanges will establish which securities will be included as Pilot Securities for purposes of the Plan. NYSE MKT and the other Participants have determined that members should use the Pilot Securities list for data collection purposes once it becomes available. Thus, the proposed rule change requires that, beginning thirty days prior to the first day of the Pilot Period—*i.e.,* September 3, 2016—NYSE MKT and NYSE MKT members will comply with the data collection obligations of the Plan by collecting data

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As noted in Item 2 of this filing, NYSE MKT has filed the proposed rule change for immediate effectiveness. NYSE MKT has requested that the SEC waive the 30-day operative period so that the proposed rule change can become operative on August 30, 2016.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[21] in general, and furthers the objectives of Section 6(b)(5) of the Act[22] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

NYSE MKT believes that this proposal is consistent with the Act because it implements and clarifies the provisions of the Plan, and is designed to assist NYSE MKT in meeting its regulatory obligations pursuant to the Plan. In approving the Plan, the SEC noted that the Pilot was an appropriate, data-driven test that was designed to evaluate the impact of a wider tick size on trading, liquidity, and the market quality of securities of smaller capitalization companies, and was therefore in furtherance of the purposes of the Act. NYSE MKT believes that this proposal is in furtherance of the objectives of the Plan, as identified by the SEC, and is therefore consistent with the Act because the proposal implements and clarifies the requirements of the Plan.

B. Self-Regulatory Organization's Statement on Burden on Competition

NYSE MKT notes that the proposed rule change implements the provisions of the Plan, and is designed to assist NYSE MKT in meeting its regulatory obligations pursuant to the Plan. NYSE MKT also notes that, other than the change to require use of the Pilot Securities beginning thirty days prior to the beginning of the Pilot Period, the proposed changes will only affect how NYSE MKT and Participants that operate Trading Centers collect and report data. NYSE MKT notes that, with respect to the change to require the use of the Pilot Securities beginning thirty days prior to the start of the Pilot Period, the proposed change reduces the number of securities on which affected members otherwise would have been required to collect data pursuant to the Plan and NYSE MKT Rule 67—Equities. In addition, the proposed rule change applies equally to all similarly situated members. Therefore, NYSE MKT does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[23] and Rule 19b–4(f)(6) thereunder.[24] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) by its terms, become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest.

A proposed rule change filed under Rule 19b–4(f)(6)[25] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[26] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30 day operative delay is consistent with the protection of investors and the public interest because it will allow the Exchange to implement the proposed rules immediately thereby preventing delays in the implementation of the Plan. The Commission notes that the Plan is scheduled to start on October 3, 2016. Therefore, the Commission hereby waives the 30 day operative delay and designates the proposed rule change to be operative upon filing with the Commission.[27]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[28] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEMKT–2016–84 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2016–84. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the

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on the Pilot Securities. As a result, beginning on September 3, 2016, members must migrate from using NYSE MKT's published Pre-Pilot Data Collection Security list and begin using the Pilot Securities list. September 2, 2016 will be the last day that members use the Pre-Pilot Data Collection Security list.

[21] 15 U.S.C. 78f(b).

[22] 15 U.S.C. 78f(b)(5).

[23] 15 U.S.C. 78s(b)(3)(A)(iii).

[24] 17 CFR 240.19b–4(f)(6).

[25] 17 CFR 240.19b–4(f)(6).

[26] 17 CFR 240.19b–4(f)(6)(iii).

[27] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[28] 15 U.S.C. 78s(b)(2)(B).

public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange.

All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2016–84 and should be submitted on or before October 7, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–22256 Filed 9–15–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78816; File No. SR–NASDAQ–2016–123]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 4770

September 12, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 29, 2016, The NASDAQ Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 4770 to modify certain data collection requirements of the Regulation NMS Plan to Implement a Tick Size Pilot Program.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On August 25, 2014, Nasdaq and several other self-regulatory organizations (the "Participants") filed with the Commission, pursuant to Section 11A of the Act[3] and Rule 608 of Regulation NMS thereunder,[4] the Plan to Implement a Tick Size Pilot Program (the "Plan").[5] The Participants filed the Plan to comply with an order issued by the Commission on June 24, 2014.[6] The Plan was published for comment in the **Federal Register** on November 7, 2014, and approved by the Commission, as modified, on May 6, 2015.[7]

The Plan is designed to allow the Commission, market participants, and the public to study and assess the impact of increment conventions on the liquidity and trading of the common stock of small-capitalization companies. Each Participant is required to comply, and to enforce compliance by its member organizations, as applicable, with the provisions of the Plan.

The Plan provides for the creation of a group of Pilot Securities, which shall be placed in a control group and three separate test groups, with each subject to varying quoting and trading increments. Pilot Securities in the control group will be quoted at the current tick size increment of $0.01 per share and will trade at the currently permitted increments. Pilot Securities in the first test group will be quoted in $0.05 minimum increments but will continue to trade at any price increment that is currently permitted.[8] Pilot Securities in the second test group ("Test Group Two") will be quoted in $0.05 minimum increments and will trade at $0.05 minimum increments subject to a midpoint exception, a retail investor order exception, and a negotiated trade exception.[9] Pilot Securities in the third test group ("Test Group Three") will be subject to the same quoting and trading increments as Test Group Two, and also will be subject to the "Trade-at" requirement to prevent price matching by a market participant that is not displaying at the price of a Trading Center's "Best Protected Bid" or "Best Protected Offer," unless an enumerated exception applies.[10] In addition to the exceptions provided under Test Group Two, an exception for Block Size orders and exceptions that mirror those under Rule 611 of Regulation NMS[11] will apply to the Trade-at requirement.

The Plan also requires a Trading Center[12] or a Market Maker[13] to collect and transmit certain data to its designated examining authority ("DEA"), and requires DEAs to transmit this data to the Commission. Participants that operate a Trading Center also are required under the Plan to collect certain data, which is then transmitted directly to the Commission. With respect to Trading Centers, Appendix B.I to the Plan (Market Quality Statistics) requires a Trading Center to submit to the Participant that is its DEA a variety of market quality statistics. Appendix B.II to the Plan (Market and Marketable Limit Order Data) requires a Trading Center to submit information to its DEA relating to market orders and marketable limit orders, including the time of order receipt, order type, the order size, and the National Best Bid or National Best Offer ("NBBO") quoted price.

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[29] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78k–1.

[4] 17 CFR 242.608.

[5] *See* Letter from Brendon J. Weiss, Vice President, Intercontinental Exchange, Inc., to Secretary, Commission, dated August 25, 2014.

[6] *See* Securities Exchange Act Release No. 72460 (June 24, 2014), 79 FR 36840 (June 30, 2014).

[7] *See* Securities Exchange Act Release No. 74892 (May 6, 2015), 80 FR 27513 (May 13, 2015) ("Approval Order").

[8] *See* Section VI(B) of the Plan.

[9] *See* Section VI(C) of the Plan.

[10] *See* Section VI(D) of the Plan.

[11] 17 CFR 242.611.

[12] The Plan incorporates the definition of a "Trading Center" from Rule 600(b)(78) of Regulation NMS. Regulation NMS defines a "Trading Center" as "a national securities exchange or national securities association that operates an SRO trading facility, an alternative trading system, an exchange market maker, an OTC market maker, or any other broker or dealer that executes orders internally by trading as principal or crossing orders as agent." *See* 17 CFR 242.600(b).

[13] The Plan defines a Market Maker as "a dealer registered with any self-regulatory organization, in accordance with the rules thereof, as (i) a market maker or (ii) a liquidity provider with an obligation to maintain continuous, two-sided trading interest."

With respect to Market Makers, Appendix B.III requires a Participant that is a national securities exchange to collect daily Market Maker Registration statistics. Appendix B.IV requires a Participant to collect data related to Market Maker participation with respect to each Market Maker engaging in trading activity on a Trading Center operated by the Participant. Appendix C.I requires a Participant to collect data related to Market Maker profitability from each Market Maker for which it is the DEA. Appendix C.II requires the Participant, as DEA, to aggregate the Appendix C.I data, and to transmit this data to the Commission.

The Commission approved the Pilot on a two-year basis, with implementation to begin no later than May 6, 2016.[14] On November 6, 2015, the SEC exempted the Participants from implementing the Pilot until October 3, 2016.[15] As set forth in Appendices B and C to the Plan, data that is reported pursuant to the appendices shall be provided for dates starting six months prior to the Pilot Period through six months after the end of the Pilot Period. Under the revised Pilot implementation date, the Pre-Pilot data collection period commenced on April 4, 2016.

On December 9, 2015, FINRA, on behalf of the Plan Participants, submitted an exemptive request to the Commission, seeking an exemption from certain data collection and reporting requirements set forth in the Plan.[16] On February 17, 2016, the Commission granted Participants exemptive relief from complying with certain data collection and reporting requirements in the Plan.[17] On March 23, 2016, the Exchange filed with the Commission a proposed rule change to adopt Rule 4770 to implement the data collection requirements of the Plan, which was effective on April 4, 2016.[18]

The Exchange now proposes to further amend Rule 4770 to modify additional data collection and reporting requirements.[19] First, Appendix B.I.a(21) through B.I.a(27) currently requires that Trading Centers report the cumulative number of shares of cancelled orders during a specified duration of time after receipt of the order that was cancelled. The Exchange and the other Participants believe that, for purposes of reporting cancelled orders, it is appropriate to categorize unexecuted Immediate or Cancel orders separately as one bucket irrespective of the duration of time after order receipt, *i.e.*, without a time increment, to better differentiate orders cancelled subsequent to entry from those where the customer's intent prior to order entry was to cancel the order if no execution could be immediately obtained. The Exchange, therefore, proposes to modify Commentary .04 to provide that unexecuted Immediate or Cancel orders shall be categorized separately for purposes of Appendix B.I.a(21) through B.I.a(27).

The second change relates to the reporting of daily market quality statistics pursuant to Appendix B.I. Currently, Appendix B.I sets forth categories of orders, including market orders, marketable limit orders, and inside-the-quote resting limit orders, for which daily market quality statistics must be reported. The Exchange and the other Participants have determined that it is appropriate to include an order type for limit orders priced more than $0.10 away from the NBBO for purposes of Appendix B reporting. The Exchange therefore proposes to amend Commentary .06 to provide that limit orders priced more than $0.10 away from the NBBO shall be included as an order type for purposes of Appendix B reporting, and shall be assigned the number (22). These orders are not currently required to be reported pursuant to Appendix B, and the Exchange and the other Participants believe that requiring the reporting of such orders will produce a more comprehensive data set.

The third change relates to the reporting of market quality statistics pursuant to Appendix B.I for a variety of order types, including inside-the-quote resting limit orders (12), at-the-quote resting limit orders (13), and near-the-quote resting limit orders (within $0.10 of the NBBO) (14). The Exchange and the other Participants believe that it is appropriate to require Trading Centers to report all orders that fall within these categories, and not just those orders that are "resting." The Exchange, therefore, proposes to amend Commentary .06 to make this change.

In the fourth change, the Exchange proposes to add new Commentary .09 to modify the manner in which market maker participation statistics are calculated. Currently, Appendix B.IV provides that market maker participation statistics shall be calculated based on share participation, trade participation, cross-quote share (trade) participation, inside-the-quote share (trade) participation, at-the-quote share (trade) participation, and outside-the-quote share (trade) participation. The Exchange and the other Participants have determined that it is appropriate to add the count of the number of Market Makers used in the calculation of share (trade) participation to each category. The Exchange is therefore proposing this change as part of Commentary .09. In addition, Appendix B.IV(b) and (c) currently require that, when aggregating across Market Makers, share participation and trade participation shall be calculated using the share-weighted average and trade-weighted average, respectively. The Exchange and the other Participants believe that it is more appropriate to calculate share and trade participation by providing the total count of shares or trades, as applicable, rather than weighted averages, and the Exchange is therefore proposing this change as part of Commentary .09.

The fifth change relates to the NBBO that a Trading Center is required to use when performing certain quote-related calculations. When calculating cross-quote share (trade) participation pursuant to Appendix B.IV(d) and inside-the-quote share (trade) participation pursuant to Appendix B.IV(e), the Plan requires the Trading Center to utilize the NBBO at the time of the trade for both share and trade participation calculations. When calculating at-the-quote share (trade) participation and outside-the quote share (trade) participation pursuant to Appendix B.IV(f) and (g), the Plan allows the Trading Center to utilize the NBBO at the time of or immediately before the trade for both share and trade participation calculations. The Exchange and the other Participants believe that it is appropriate to calculate all quote participation (cross-quote share (trade) participation, inside-the-quote share (trade) participation, at-the-quote share (trade) participation and outside-the-quote share (trade) participation) solely by reference to the

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[14] *See* Approval Order at 27533 and 27545.

[15] *See* Securities Exchange Act Release No. 76382 (November 6, 2015), 80 FR 70284 (November 13, 2015) (File No. 4–657).

[16] *See* Letter from Marcia E. Asquith, Senior Vice President and Corporate Secretary, FINRA, to Robert W. Errett, Deputy Secretary, Commission, dated December 9, 2015 ("Exemptive Request").

[17] *See* Letter from David S. Shillman, Associate Director, Division of Trading and Markets, Commission, to Marcia E. Asquith, Senior Vice President and Corporate Secretary, FINRA, dated February 17, 2016.

[18] *See* Securities Exchange Act Release No. 77456 (March 28, 2016), 81 FR 18925 (April 1, 2016) (SR–NASDAQ–2016–023) [sic].

[19] In connection with this proposed rule change and others made by Participants, FINRA intends to file an exemptive request on behalf of Participants seeking relief from certain of the Plan's data collection requirements.

NBBO in effect immediately prior to the trade. The Exchange, therefore, proposes to make this change as part of Commentary .09.

Finally, the Exchange proposes to change the end date until which the Pre-Pilot Data Collection Securities shall be used to fulfill the Plan's data collection requirements. Currently, Commentary .10 provides that Pre-Pilot Data Collection Securities are the securities designated by the Participants for purposes of the data collection requirements described in Items I, II and IV of Appendix B and Item I of Appendix C to the Plan for the period beginning six months prior to the Pilot Period and ending on the trading day immediately preceding the Pilot Period. The Exchange and the other Participants believe that it is appropriate to use the Pilot Securities to satisfy the Plan's data collection requirements prior to the commencement of the Pilot. Accordingly, the Exchange is revising Commentary .10 (which will be re-numbered as Commentary .11) to provide that the Pre-Pilot Data Collection Securities shall be used to satisfy the Plan's data collection requirements through thirty-one days prior to the Pilot Period, after which time the Pilot Securities shall be used for purposes of the data collection requirements.[20] As noted in Item 2 of this filing, the Exchange has filed the proposed rule change for immediate effectiveness. The Exchange has requested that the SEC waive the 30-day operative period so that the proposed rule change can become operative on August 30, 2016.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[21] in general, and furthers the objectives of Section 6(b)(5) of the Act,[22] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, and Section 6(b)(8) of the Act,[23] which requires that the Exchange not impose any burden on competition that is not necessary or appropriate.

The Exchange believes that this proposal is consistent with the Act because it implements and clarifies the provisions of the Plan, and is designed to assist the Exchange in meeting its regulatory obligations pursuant to the Plan. In approving the Plan, the SEC noted that the Pilot was an appropriate, data-driven test that was designed to evaluate the impact of a wider tick size on trading, liquidity, and the market quality of securities of smaller capitalization companies, and was therefore in furtherance of the purposes of the Act. The Exchange believes that this proposal is in furtherance of the objectives of the Plan, as identified by the SEC, and is therefore consistent with the Act because the proposal implements and clarifies the requirements of the Plan.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that the proposed rule change implements the provisions of the Plan, and is designed to assist the Exchange in meeting its regulatory obligations pursuant to the Plan. The Exchange also notes that, other than the change to require use of the Pilot Securities beginning thirty days prior to the beginning of the Pilot Period, the proposed changes will not affect the data collection and reporting requirements for members that operate Trading Centers; the proposed changes will only affect how the Exchange and Participants that operate Trading Centers collect and report data. The Exchange notes that, with respect to the change to require the use of the Pilot Securities beginning thirty days prior to the start of the Pilot Period, the proposed change reduces the number of securities on which affected members otherwise would have been required to collect data pursuant to the Plan and Rule 4770. In addition, the proposed rule change applies equally to all similarly situated members. Therefore, the Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[24] and Rule 19b–4(f)(6)[25] thereunder because the proposal does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) by its terms, become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest.

A proposed rule change filed under Rule 19b–4(f)(6)[26] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[27] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that so that the proposed rule change can become operative on August 30, 2016.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because it will allow the Exchange to implement the proposed rules immediately thereby preventing delays in the implementation of the Plan. The Commission notes that the Plan is scheduled to start on October 3, 2016. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change to be operative upon filing with the Commission.[28]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.[29]

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[20] After regular trading hours on September 2, 2016, the national securities exchanges will establish which securities will be included as Pilot Securities for purposes of the Plan. The Exchange and the other Participants have determined that members should use the Pilot Securities list for data collection purposes once it becomes available. Thus, the proposed rule change requires that, beginning thirty days prior to the first day of the Pilot Period—*i.e.,* September 3, 2016—The Exchange and Exchange members will comply with the data collection obligations of the Plan by collecting data on the Pilot Securities. As a result, beginning on September 3, 2016, members must migrate from using the Exchange's published Pre-Pilot Data Collection Security list and begin using the Pilot Securities list. September 2, 2016 will be the last day that members use the Pre-Pilot Data Collection Security list.

[21] 15 U.S.C. 78f(b).

[22] 15 U.S.C. 78f(b)(5).

[23] 15 U.S.C. 78f(b)(8).

[24] 15 U.S.C. 78s(b)(3)(A).

[25] 17 CFR 240.19b–4(f)(6).

[26] 17 CFR 240.19b–4(f)(6).

[27] 17 CFR 240.19b–4(f)(6)(iii).

[28] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2016–123 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2016–123. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2016–123 and should be submitted on or before October 7, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–22255 Filed 9–15–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78814; File No. SR–NYSEARCA–2016–124]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.46 To Modify Certain Data Collection Requirements of the Regulation NMS Plan To Implement a Tick Size Pilot Program

September 12, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on August 29, 2016, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.46 to modify certain data collection requirements of the Regulation NMS Plan to Implement a Tick Size Pilot Program. The proposed rule change is available on the Exchange's Web site at *www.nyse.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

On August 25, 2014, NYSE Arca, and several other self-regulatory organizations (the "Participants") filed with the Commission, pursuant to Section 11A of the Act[4] and Rule 608 of Regulation NMS thereunder,[5] the Plan to Implement a Tick Size Pilot Program (the "Plan").[6] The Participants filed the Plan to comply with an order issued by the Commission on June 24, 2014.[7] The Plan was published for comment in the **Federal Register** on November 7, 2014, and approved by the Commission, as modified, on May 6, 2015.[8]

The Plan is designed to allow the Commission, market participants, and the public to study and assess the impact of increment conventions on the liquidity and trading of the common stock of small-capitalization companies. Each Participant is required to comply, and to enforce compliance by its member organizations, as applicable, with the provisions of the Plan.

The Plan provides for the creation of a group of Pilot Securities, which shall be placed in a control group and three separate test groups, with each subject to varying quoting and trading increments. Pilot Securities in the control group will be quoted at the current tick size increment of $0.01 per share and will trade at the currently permitted increments. Pilot Securities in the first test group will be quoted in $0.05 minimum increments but will continue to trade at any price increment that is currently permitted.[9] Pilot Securities in the second test group ("Test Group Two") will be quoted in $0.05 minimum increments and will trade at $0.05 minimum increments subject to a midpoint exception, a retail investor order exception, and a negotiated trade exception.[10] Pilot Securities in the third test group ("Test Group Three") will be subject to the same quoting and trading increments as Test Group Two, and also will be subject to the "Trade-at" requirement to prevent price matching by a market participant that is not displaying at the price of a Trading Center's "Best Protected Bid" or "Best Protected Offer," unless an enumerated exception applies.[11] In addition to the exceptions provided under Test Group Two, an exception for Block Size orders and exceptions that mirror those under Rule 611 of Regulation NMS[12] will apply to the Trade-at requirement.

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[29] 15 U.S.C. 78s(b)(3)(C).

[30] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78k–1.

[5] 17 CFR 242.608.

[6] *See* Letter from Brendon J. Weiss, Vice President, Intercontinental Exchange, Inc., to Secretary, Commission, dated August 25, 2014.

[7] *See* Securities Exchange Act Release No 72460 (June 24, 2014), 79 FR 36840 (June 30, 2014).

[8] *See* Securities Exchange Act Release No. 74892 (May 6, 2015), 80 FR 27513 (May 13, 2015) ("Approval Order").

[9] *See* Section VI(B) of the Plan.

The Plan also requires a Trading Center[13] or a Market Maker[14] to collect and transmit certain data to its designated examining authority ("DEA"), and requires DEAs to transmit this data to the Commission. Participants that operate a Trading Center also are required under the Plan to collect certain data, which is then transmitted directly to the Commission. With respect to Trading Centers, Appendix B.I to the Plan (Market Quality Statistics) requires a Trading Center to submit to the Participant that is its DEA a variety of market quality statistics. Appendix B.II to the Plan (Market and Marketable Limit Order Data) requires a Trading Center to submit information to its DEA relating to market orders and marketable limit orders, including the time of order receipt, order type, the order size, and the National Best Bid and National Best Offer quoted price.

With respect to Market Makers, Appendix B.III requires a Participant that is a national securities exchange to collect daily Market Maker Registration statistics. Appendix B.IV requires a Participant to collect data related to Market Maker participation with respect to each Market Maker engaging in trading activity on a Trading Center operated by the Participant. Appendix C.I requires a Participant to collect data related to Market Maker profitability from each Market Maker for which it is the DEA. Appendix C.II requires the Participant, as DEA, to aggregate the Appendix C.I data, and to transmit this data to the Commission.

The Commission approved the Pilot on a two-year basis, with implementation to begin no later than May 6, 2016.[15] On November 6, 2015, the SEC exempted the Participants from implementing the pilot until October 3, 2016.[16] As set forth in Appendices B and C to the Plan, data that is reported pursuant to the appendices shall be provided for dates starting six months prior to the Pilot Period through six months after the end of the Pilot Period. Under the revised Pilot implementation date, the Pre-Pilot data collection period commenced on April 4, 2016.

On March 29, 2016, NYSE Arca filed with the Commission a proposed rule change to adopt NYSE Arca Rule 7.46(b) to implement the data collection requirements of the Plan.[17] On December 9, 2015, NYSE Arca submitted an exemptive request to the Commission, seeking an exemption from certain data collection and reporting requirements set forth in the Plan.[18] On April 4, 2016, the Commission granted exemptive relief from complying with certain data collection and reporting requirements in the Plan.[19]

NYSE Arca now proposes to further amend Rule 7.46 to modify additional data collection and reporting requirements. First, Appendix B.I.a(21) through B.I.a(27) currently requires that Trading Centers report the cumulative number of shares of cancelled orders during a specified duration of time after receipt of the order that was cancelled. NYSE Arca and the other Participants believe that, for purposes of reporting cancelled orders, it is appropriate to categorize unexecuted Immediate or Cancel orders separately as one bucket irrespective of the duration of time after order receipt, *i.e.*, without a time increment, to better differentiate orders cancelled subsequent to entry from those where the customer's intent prior to order entry was to cancel the order if no execution could be immediately obtained. NYSE Arca, therefore, proposes to modify Supplementary Material .30 to provide that unexecuted Immediate or Cancel orders shall be categorized separately for purposes of Appendix B.I.a(21) through B.I.a(27).

The second change relates to the reporting of daily market quality statistics pursuant to Appendix B.I. Currently, Appendix B.I sets forth categories of orders, including market orders, marketable limit orders, and inside-the-quote resting limit orders, for which daily market quality statistics must be reported. NYSE Arca and the other Participants have determined that it is appropriate to include an order type for limit orders priced more than $0.10 away from the NBBO for purposes of Appendix B reporting. NYSE Arca therefore proposes to amend Supplementary Material .50 to provide that limit orders priced more than $0.10 away from the NBBO shall be included as an order type for purposes of Appendix B reporting, and shall be assigned the number (22). These orders are not currently required to be reported pursuant to Appendix B, and NYSE Arca and the other Participants believe that requiring the reporting of such orders will produce a more comprehensive data set.

The third change relates to the reporting of market quality statistics pursuant to Appendix B.I for a variety of order types, including inside-the-quote resting limit orders (12), at-the-quote resting limit orders (13), and near-the-quote resting limit orders (within $0.10 of the NBBO) (14). NYSE Arca and the other Participants believe that it is appropriate to require Trading Centers to report all orders that fall within these categories, and not just those orders that are "resting." NYSE Arca, therefore, proposes to amend Supplementary Material .50 to make this change.

In the fourth change, NYSE Arca proposes to add new Supplementary Material .100 to modify the manner in which market maker participation statistics are calculated. Currently, Appendix B.IV provides that market maker participation statistics shall be calculated based on share participation, trade participation, cross-quote share (trade) participation, inside-the-quote share (trade) participation, at-the-quote share (trade) participation, and outside-the-quote share (trade) participation. NYSE Arca and the other Participants have determined that it is appropriate to add the count of the number of Market Makers used in the calculation of share (trade) participation to each category. NYSE Arca is therefore proposing this change as part of Supplementary Material .100. In addition, Appendix B.IV(b) and (c) currently require that, when aggregating across Market Makers, share participation and trade participation shall be calculated using the share-weighted average and trade-weighted average, respectively. NYSE Arca and the other Participants believe that it is more appropriate to calculate share and trade participation by providing the total count of shares or trades, as applicable, rather than weighted averages, and NYSE Arca is therefore proposing this change as part of Supplementary Material .100.

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[10] *See* Section VI(C) of the Plan.

[11] *See* Section VI(D) of the Plan.

[12] 17 CFR 242.611.

[13] The Plan incorporates the definition of a "Trading Center" from Rule 600(b)(78) of Regulation NMS. Regulation NMS defines a "Trading Center" as "a national securities exchange or national securities association that operates an SRO trading facility, an alternative trading system, an exchange market maker, an OTC market maker, or any other broker or dealer that executes orders internally by trading as principal or crossing orders as agent." *See* 17 CFR 242.600(b).

[14] The Plan defines a Market Maker as "a dealer registered with any self-regulatory organization, in accordance with the rules thereof, as (i) a market maker or (ii) a liquidity provider with an obligation to maintain continuous, two-sided trading interest."

[15] *See* Approval Order at 27533 and 27545.

[16] *See* Securities Exchange Act Release No. 76382 (November 6, 2015), 80 FR 70284 (November 13, 2015) (File No. 4–657).

[17] *See* Securities Exchange Act Release No. 77484 (March 31, 2016), 81 FR 20024 (April 6, 2016) (Immediate Effectiveness of Proposed Rule Change Adopting Requirements for the Collection and Transmission of Data Pursuant to Appendices B and C of the Regulation NMS Plan to Implement a Tick Size Pilot Program) (SR–NYSEARCA–2016–52).

NYSE Arca also submitted a proposed rule change to implement the quoting and trading requirements of the Plan. *See* Securities Exchange Act Release No. 77947 (May 31, 2016), 81 FR 36361 (June 6, 2016) (Immediate Effectiveness of Proposed Rule Change Implementing the Quoting and Trading Provisions of the Plan to Implement a Tick Size Pilot Program) (SR–NYSEARCA–2016–76).

[18] *See* Letter from Marcia E. Asquith, Senior Vice President and Corporate Secretary, FINRA, to Robert W. Errett, Deputy Secretary, Commission, dated December 9, 2015 ("Exemptive Request").

[19] *See* letter from John C. Roeser, Associate Director, Division of Trading and Markets, Commission, to Sherry Sandler, Associate General Counsel, NYSE Arca, dated April 4, 2016.

The fifth change relates to the NBBO that a Trading Center is required to use when performing certain quote-related calculations. When calculating cross-quote share (trade) participation pursuant to Appendix B.IV(d) and inside-the-quote share (trade) participation pursuant to Appendix B.IV(e), the Plan requires the Trading Center to utilize the NBBO at the time of the trade for both share and trade participation calculations. When calculating at-the-quote share (trade) participation and outside-the-quote share (trade) participation pursuant to Appendix B.IV(f) and (g), the Plan allows the Trading Center to utilize the National Best Bid or National Best Offer (NBBO) at the time of or immediately before the trade for both share and trade participation calculations. NYSE Arca and the other Participants believe that it is appropriate to calculate all quote participation (cross-quote share (trade) participation, inside-the-quote share (trade) participation, at-the-quote share (trade) participation and outside-the-quote share (trade) participation) solely by reference to the NBBO in effect immediately prior to the trade. NYSE Arca therefore proposes to make this change as part of Supplementary Material .100.

Finally, NYSE Arca proposes to change the end date until which the Pre-Pilot Data Collection Securities shall be used to fulfill the Plan's data collection requirements. Currently, Supplementary Material .90 provides that Pre-Pilot Data Collection Securities are the securities designated by the Participants for purposes of the data collection requirements described in Items I, II and IV of Appendix B and Item I of Appendix C to the Plan for the period beginning six months prior to the Pilot Period and ending on the trading day immediately preceding the Pilot Period. NYSE Arca the other Participants believe that it is appropriate to use the Pilot Securities to satisfy the Plan's data collection requirements prior to the commencement of the Pilot. According, NYSE Arca is revising Supplementary Material .90 to provide that the Pre-Pilot Data Collection Securities shall be used to satisfy the Plan's data collection requirements through thirty-one days prior to the Pilot Period, after which time the Pilot Securities shall be used for purposes of the data collection requirements.[20]

As noted in Item 2 of this filing, NYSE Arca has filed the proposed rule change for immediate effectiveness. NYSE Arca has requested that the SEC waive the 30-day operative period so that the proposed rule change can become operative on August 30, 2016.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[21] in general, and furthers the objectives of Section 6(b)(5) of the Act[22] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

NYSE Arca believes that this proposal is consistent with the Act because it implements and clarifies the provisions of the Plan, and is designed to assist NYSE Arca in meeting its regulatory obligations pursuant to the Plan. In approving the Plan, the SEC noted that the Pilot was an appropriate, data-driven test that was designed to evaluate the impact of a wider tick size on trading, liquidity, and the market quality of securities of smaller capitalization companies, and was therefore in furtherance of the purposes of the Act. NYSE Arca believes that this proposal is in furtherance of the objectives of the Plan, as identified by the SEC, and is therefore consistent with the Act because the proposal implements and clarifies the requirements of the Plan.

B. Self-Regulatory Organization's Statement on Burden on Competition

NYSE Arca notes that the proposed rule change implements the provisions of the Plan, and is designed to assist NYSE Arca in meeting its regulatory obligations pursuant to the Plan. NYSE Arca also notes that, other than the change to require use of the Pilot Securities beginning thirty days prior to the beginning of the Pilot Period, the proposed changes will only affect how NYSE Arca and Participants that operate Trading Centers collect and report data. NYSE Arca notes that, with respect to the change to require the use of the Pilot Securities beginning thirty days prior to the start of the Pilot Period, the proposed change reduces the number of securities on which affected ETP Holders otherwise would have been required to collect data pursuant to the Plan and NYSE Arca Rule 7.46. In addition, the proposed rule change applies equally to all similarly situated ETP Holders. Therefore, NYSE Arca does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[23] and Rule 19b–4(f)(6) thereunder.[24] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) by its terms, become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest.

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[20] After regular trading hours on September 2, 2016, the national securities exchanges will establish which securities will be included as Pilot Securities for purposes of the Plan. NYSE Arca and the other Participants have determined that members should use the Pilot Securities list for data collection purposes once it becomes available. Thus, the proposed rule change requires that, beginning thirty days prior to the first day of the Pilot Period—*i.e.,* September 3, 2016—NYSE Arca and NYSE Arca ETP Holders will comply with the data collection obligations of the Plan by collecting data on the Pilot Securities. As a result, beginning on September 3, 2016, ETP Holders must migrate from using NYSE Arca's published Pre-Pilot Data Collection Security list and begin using the Pilot Securities list. September 2, 2016 will be the last day that ETP Holders use the Pre-Pilot Data Collection Security list.

[21] 15 U.S.C. 78f(b).

[22] 15 U.S.C. 78f(b)(5).

[23] 15 U.S.C. 78s(b)(3)(A)(iii).

[24] 17 CFR 240.19b–4(f)(6).

A proposed rule change filed under Rule 19b–4(f)(6)[25] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[26] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30 day operative delay is consistent with the protection of investors and the public interest because it will allow the Exchange to implement the proposed rules immediately thereby preventing delays in the implementation of the Plan. The Commission notes that the Plan is scheduled to start on October 3, 2016. Therefore, the Commission hereby waives the 30 day operative delay and designates the proposed rule change to be operative upon filing with the Commission.[27]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[28] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEARCA–2016–124 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2016–124. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2016–124 and should be submitted on or before October 7, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–22253 Filed 9–15–16; 8:45 am]

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[25] 17 CFR 240.19b–4(f)(6).

[26] 17 CFR 240.19b–4(f)(6)(iii).

[27] For Purposes only of waiving the operative delay for this proposal the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[28] 15 U.S.C. 78s(b)(2)(B).

[29] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78812; File No. SR–CHX–2016–17]

Self Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Article 20, Rule 13(b) To Modify Certain Data Collection Requirements of the Regulation NMS Plan To Implement a Tick Size Pilot Program

September 12, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4[2] thereunder, notice is hereby given that on August 29, 2016, the Chicago Stock Exchange, Inc. ("CHX" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CHX proposes to amend Article 20, Rule 13(b) to modify certain data collection requirements of the Regulation NMS Plan to Implement a Tick Size Pilot Program.

CHX has designated this proposed rule change as non-controversial pursuant to Section 19(b)(3)(A)[3] of the Act and Rule 19b–4(f)(6)[4] thereunder and has provided the Commission with the notice required by Rule 19b–4(f)(6)(iii).[5]

The text of this proposed rule change is available on the Exchange's Web site at (*www.chx.com*) and in the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CHX included statements concerning the purpose of and basis for the proposed rule changes and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CHX has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] 17 CFR 240.19b–4(f)(6)(iii).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Changes

1. Purpose

On August 25, 2014, the Exchange, and several other self-regulatory organizations (the "Plan Participants"[6]) filed with the Commission, pursuant to Section 11A of the Act[7] and Rule 608 of Regulation NMS thereunder,[8] the Plan to Implement a Tick Size Pilot Program (the "Plan").[9] The Plan Participants filed the Plan to comply with an order issued by the Commission on June 24, 2014.[10] The Plan[11] was published for comment in the **Federal Register** on November 7, 2014, and approved by the Commission, as modified, on May 6, 2015.[12]

The Plan is designed to allow the Commission, market participants, and the public to study and assess the impact of increment conventions on the liquidity and trading of the common stocks of small-capitalization companies. Each Plan Participant is required to comply, and to enforce compliance by its members, as applicable, with the provisions of the Plan.

The Plan provides for the creation of a group of Pilot Securities, which shall be placed in a control group and three separate test groups, with each subject to varying quoting and trading increments. Pilot Securities in the control group will be quoted at the current tick size increment of $0.01 per share and will trade at the currently permitted increments. Pilot Securities in the first test group will be quoted in $0.05 minimum increments but will continue to trade at any price increment that is currently permitted.[13] Pilot Securities in the second test group ("Test Group Two") will be quoted in $0.05 minimum increments and will trade at $0.05 minimum increments subject to a midpoint exception, a retail investor order exception, and a negotiated trade exception.[14] Pilot Securities in the third test group ("Test Group Three") will be subject to the same quoting and trading increments as Test Group Two, and also will be subject to the "Trade-at" requirement to prevent price matching by a market participant that is not displaying at the price of a Trading Center's "Best Protected Bid" or "Best Protected Offer," unless an enumerated exception applies.[15] In addition to the exceptions provided under Test Group Two, an exception for Block Size orders and exceptions that mirror those under Rule 611 of Regulation NMS[16] will apply to the Trade-at requirement.

The Plan also requires a Trading Center[17] or a Market Maker[18] to collect and transmit certain data to its designated examining authority ("DEA"), and requires DEAs to transmit this data to the Commission. Plan Participants that operate a Trading Center also are required under the Plan to collect certain data, which is then transmitted directly to the Commission. With respect to Trading Centers, Appendix B.I to the Plan (Market Quality Statistics) requires a Trading Center to submit to the Plan Participant that is its DEA a variety of market quality statistics. Appendix B.II to the Plan (Market and Marketable Limit Order Data) requires a Trading Center to submit information to its DEA relating to market orders and marketable limit orders, including the time of order receipt, order type, the order size, and the National Best Bid and National Best Offer quoted price.

With respect to Market Makers, Appendix B.III requires a Plan Participant that is a national securities exchange to collect daily Market Maker Registration statistics. Appendix B.IV requires a Plan Participant to collect data related to Market Maker participation with respect to each Market Maker engaging in trading activity on a Trading Center operated by the Plan Participant. Appendix C.I requires a Plan Participant to collect data related to Market Maker profitability from each Market Maker for which it is the DEA. Appendix C.II requires the Plan Participant, as DEA, to aggregate the Appendix C.I data, and to transmit this data to the Commission.

The Commission approved the Pilot on a two-year basis, with implementation to begin no later than May 6, 2016.[19] On November 6, 2015, the SEC exempted the Plan Participants from implementing the pilot until October 3, 2016.[20] As set forth in Appendices B and C to the Plan, data that is reported pursuant to the appendices shall be provided for dates starting six months prior to the Pilot Period through six months after the end of the Pilot Period. Under the revised Pilot implementation date, the Pre-Pilot data collection period commenced on April 4, 2016.

On March 28, 2016, the Exchange filed with the Commission a proposed rule change to adopt Article 20, Rule 13(b) to implement the data collection requirements of the Plan, which was immediately effective upon filing.[21] On December 9, 2015, FINRA, on behalf of the Plan Participants, submitted an exemptive request to the Commission, seeking an exemption from certain data collection and reporting requirements set forth in the Plan.[22]

The Exchange now proposes to further amend Article 20, Rule 13(b) to modify additional data collection and reporting requirements.[23] First,

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[6] A "Participant" is a "member" of the Exchange for purposes of the Act. *See* CHX Article 1, Rule 1(s). For clarity, the Exchange proposes to utilize the term "CHX Participant" when referring to members of the Exchange and the term "Plan Participant" when referring to Participants of the Plan.

[7] 15 U.S.C. 78k–1.

[8] 17 CFR 242.608.

[9] *See* Letter from Brendon J. Weiss, Vice President, Intercontinental Exchange, Inc., to Secretary, Commission, dated August 25, 2014.

[10] *See* Securities Exchange Act Release No. 72460 (June 24, 2014), 79 FR 36840 (June 30, 2014).

[11] Unless otherwise specified, capitalized terms used in this rule filing are based on the defined terms of the Plan.

[12] *See* Securities Exchange Act Release No. 74892 (May 6, 2015), 80 FR 27513 (May 13, 2015) ("Approval Order").

[13] *See* Section VI(B) of the Plan.

[14] *See* Section VI(C) of the Plan.

[15] *See* Section VI(D) of the Plan.

[16] 17 CFR 242.611.

[17] The Plan incorporates the definition of a "Trading Center" from Rule 600(b)(78) of Regulation NMS. Regulation NMS defines a "Trading Center" as "a national securities exchange or national securities association that operates an SRO trading facility, an alternative trading system, an exchange market maker, an OTC market maker, or any other broker or dealer that executes orders internally by trading as principal or crossing orders as agent." *See* 17 CFR 242.600(b).

[18] The Plan defines a Market Maker as "a dealer registered with any self-regulatory organization, in accordance with the rules thereof, as (i) a market maker or (ii) a liquidity provider with an obligation to maintain continuous, two-sided trading interest."

[19] *See* Approval Order at 27533 and 27545.

[20] *See* Securities Exchange Act Release No. 76382 (November 6, 2015), 80 FR 70284 (November 13, 2015) (File No. 4–657).

[21] *See* Securities Exchange Act Release No. 77469 (March 29, 2016), 81 FR 19275 (April 4, 2016) (SR–CHX–2016–03).

The Exchange also submitted a proposed rule change to implement the quoting and trading requirements of the Plan. *See* Securities Exchange Act Release No. 78146 (June 23, 2016), 81 FR 42380 (June 29, 2016) (SR–CHX–2016–09).

[22] *See* Letter from Marcia E. Asquith, Senior Vice President and Corporate Secretary, FINRA, to Robert W. Errett, Deputy Secretary, Commission, dated December 9, 2015 ("Exemptive Request"). The Commission, pursuant to its authority under Rule 608(e) of Regulation NMS, granted the Exchange a limited exemption from the requirement to comply with certain provisions of the Plan as specified in the letter and noted herein. *See* letter from John C. Roeser, Associate Director, Division of Trading and Markets, Commission, to Albert Kim, Vice President and Associate General Counsel, CHX, dated April 4, 2016 ("Exemption Letter").

[23] The Exchange notes that, in connection with this proposed rule change, FINRA, on behalf of the Plan Participants, intends to file an exemptive request seeking relief from certain of the Plan's data collection requirements.

Appendix B.I.a(21) through B.I.a(27) currently requires that Trading Centers report the cumulative number of shares of cancelled orders during a specified duration of time after receipt of the order that was cancelled. The Exchange and the other Plan Participants believe that, for purposes of reporting cancelled orders, it is appropriate to categorize unexecuted Immediate or Cancel orders separately as one bucket irrespective of the duration of time after order receipt, *i.e.*, without a time increment, to better differentiate orders cancelled subsequent to entry from those where the customer's intent prior to order entry was to cancel the order if no execution could be immediately obtained. The Exchange, therefore, proposes to modify Interpretations and Policies paragraph .04 to provide that unexecuted Immediate or Cancel orders shall be categorized separately for purposes of Appendix B.I.a(21) through B.I.a(27).

The second change relates to the reporting of daily market quality statistics pursuant to Appendix B.I. Currently, Appendix B.I sets forth categories of orders, including market orders, marketable limit orders, and inside-the-quote resting limit orders, for which daily market quality statistics must be reported. The Exchange and the other Plan Participants have determined that it is appropriate to include an order type for limit orders priced more than $0.10 away from the NBBO for purposes of Appendix B reporting. The Exchange therefore proposes to amend Interpretations and Policies paragraph .06 to provide that limit orders priced more than $0.10 away from the NBBO shall be included as an order type for purposes of Appendix B reporting, and shall be assigned the number (22). These orders are not currently required to be reported pursuant to Appendix B, and the Exchange and the other Plan Participants believe that requiring the reporting of such orders will produce a more comprehensive data set.

The third change relates to the reporting of market quality statistics pursuant to Appendix B.I for a variety of order types, including inside-the-quote resting limit orders (12), at-the-quote resting limit orders (13), and near-the-quote resting limit orders (within $0.10 of the NBBO) (14). The Exchange and the other Plan Participants believe that it is appropriate to require Trading Centers to report all orders that fall within these categories, and not just those orders that are "resting." The Exchange, therefore, proposes to amend Interpretations and Policies paragraph .06 to make this change.

In the fourth change, the Exchange proposes to add new Interpretations and Policies paragraph .09 to modify the manner in which market maker participation statistics are calculated. Currently, Appendix B.IV provides that market maker participation statistics shall be calculated based on share participation, trade participation, cross-quote share (trade) participation, inside-the-quote share (trade) participation, at-the-quote share (trade) participation, and outside-the-quote share (trade) participation. The Exchange and the other Plan Participants have determined that it is appropriate to add the count of the number of Market Makers used in the calculation of share (trade) participation to each category. The Exchange is therefore proposing this change as part of Interpretations and Policies paragraph .09. In addition, Appendix B.IV(b) and (c) currently require that, when aggregating across Market Makers, share participation and trade participation shall be calculated using the share-weighted average and trade-weighted average, respectively. The Exchange and the other Plan Participants believe that it is more appropriate to calculate share and trade participation by providing the total count of shares or trades, as applicable, rather than weighted averages, and the Exchange is therefore proposing this change as part of Interpretations and Policies paragraph .09.

The fifth change relates to the NBBO that a Trading Center is required to use when performing certain quote-related calculations. When calculating cross-quote share (trade) participation pursuant to Appendix B.IV(d) and inside-the-quote share (trade) participation pursuant to Appendix B.IV(e), the Plan requires the Trading Center to utilize the NBBO at the time of the trade for both share and trade participation calculations. When calculating at-the-quote share (trade) participation and outside-the-quote share (trade) participation pursuant to Appendix B.IV(f) and (g), the Plan allows the Trading Center to utilize the National Best Bid or National Best Offer (NBBO) at the time of or immediately before the trade for both share and trade participation calculations. The Exchange and the other Plan Participants believe that it is appropriate to calculate all quote participation (cross-quote share (trade) participation, inside-the-quote share (trade) participation, at-the-quote share (trade) participation and outside-the-quote share (trade) participation) solely by reference to the NBBO in effect immediately prior to the trade. The Exchange therefore proposes to make this change as part of Interpretations and Policies paragraph .09.

Finally, the Exchange proposes to change the end date until which the Pre-Pilot Data Collection Securities shall be used to fulfill the Plan's data collection requirements. Currently, Interpretations and Policies paragraph .10 provides that Pre-Pilot Data Collection Securities are the securities designated by the Plan Participants for purposes of the data collection requirements described in Items I, II and IV of Appendix B and Item I of Appendix C to the Plan for the period beginning six months prior to the Pilot Period and ending on the trading day immediately preceding the Pilot Period. The Exchange and the other Plan Participants believe that it is appropriate to use the Pilot Securities to satisfy the Plan's data collection requirements prior to the commencement of the Pilot. According, the Exchange is revising Interpretations and Policies paragraph .10 (which will be re-numbered as Interpretations and Policies paragraph .11) to provide that the Pre-Pilot Data Collection Securities shall be used to satisfy the Plan's data collection requirements through thirty-one days prior to the Pilot Period, after which time the Pilot Securities shall be used for purposes of the data collection requirements.[24]

The Exchange has filed the proposed rule change for immediate effectiveness. The Exchange has requested that the SEC waive the 30-day operative period so that the proposed rule change can become operative on August 30, 2016.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[25] in general, and furthers the objectives of Section 6(b)(5) of the Act[26] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

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[24] After regular trading hours on September 2, 2016, the national securities exchanges will establish which securities will be included as Pilot Securities for purposes of the Plan. The Exchange and the other Plan Participants have determined that members should use the Pilot Securities list for data collection purposes once it becomes available. Thus, the proposed rule change requires that, beginning thirty days prior to the first day of the Pilot Period—*i.e.,* September 3, 2016—the Exchange and CHX Participants will comply with the data collection obligations of the Plan by collecting data on the Pilot Securities. As a result, beginning on September 3, 2016, CHX Participants must migrate from using the Exchange's published Pre-Pilot Data Collection Security list and begin using the Pilot Securities list. September 2, 2016 will be the last day that CHX Participants use the Pre-Pilot Data Collection Security list.

[25] 15 U.S.C. 78f(b).

[26] 15 U.S.C. 78f(b)(5).

The Exchange believes that this proposal is consistent with the Act because it implements and clarifies the provisions of the Plan, and is designed to assist the Exchange in meeting its regulatory obligations pursuant to the Plan. In approving the Plan, the SEC noted that the Pilot was an appropriate, data-driven test that was designed to evaluate the impact of a wider tick size on trading, liquidity, and the market quality of securities of smaller capitalization companies, and was therefore in furtherance of the purposes of the Act. The Exchange believes that this proposal is in furtherance of the objectives of the Plan, as identified by the SEC, and is therefore consistent with the Act because the proposal implements and clarifies the requirements of the Plan.

B. Self-Regulatory Organization's Statement of Burden on Competition

The Exchange notes that the proposed rule change implements the provisions of the Plan, and is designed to assist the Exchange in meeting its regulatory obligations pursuant to the Plan. The Exchange also notes that, other than the change to require use of the Pilot Securities beginning thirty days prior to the beginning of the Pilot Period, the proposed changes will not affect the data collection and reporting requirements for CHX Participants that operate Trading Centers; the proposed changes will only affect how the Exchange and Plan Participants that operate Trading Centers collect and report data. The Exchange notes that, with respect to the change to require the use of the Pilot Securities beginning thirty days prior to the start of the Pilot Period, the proposed change reduces the number of securities on which affected CHX Participants otherwise would have been required to collect data pursuant to the Plan and Article 20, Rule 13(b). In addition, the proposed rule change applies equally to all similarly situated CHX Participants. Therefore, the Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments Regarding the Proposed Rule Changes Received From Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Changes and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[27] and Rule 19b–4(f)(6)[28] thereunder because the proposal does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) by its terms, become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest.

A proposed rule change filed under Rule 19b–4(f)(6)[29] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[30] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that so that the proposed rule change can become operative on August 30, 2016.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because it will allow the Exchange to implement the proposed rules immediately thereby preventing delays in the implementation of the Plan. The Commission notes that the Plan is scheduled to start on October 3, 2016. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change to be operative upon filing with the Commission.[31]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.[32]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–CHX–2016–17 on the subject line.

Paper Comments

- Send paper comments in triplicate to Robert W. Errett, Deputy Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–CHX–2016–17. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule changes between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the CHX. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–CHX–2016–17 and should be submitted on or before October 7, 2016.

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[27] 15 U.S.C. 78s(b)(3)(A).

[28] 17 CFR 240.19b–4(f)(6).

[29] 17 CFR 240.19b–4(f)(6).

[30] 17 CFR 240.19b–4(f)(6)(iii).

[31] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[32] 15 U.S.C. 78s(b)(3)(C).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–22251 Filed 9–15–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78813; File No. SR–NYSE–2016–63]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 67 To Modify Certain Data Collection Requirements of the Regulation NMS Plan To Implement a Tick Size Pilot Program

September 12, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the “Act”)[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on August 29, 2016, New York Stock Exchange LLC (“NYSE” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 67 to modify certain data collection requirements of the Regulation NMS Plan to Implement a Tick Size Pilot Program. The proposed rule change is available on the Exchange's Web site at *www.nyse.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

On August 25, 2014, NYSE, and several other self-regulatory organizations (the “Participants”) filed with the Commission, pursuant to Section 11A of the Act[4] and Rule 608 of Regulation NMS thereunder,[5] the Plan to Implement a Tick Size Pilot Program (the “Plan”).[6] The Participants filed the Plan to comply with an order issued by the Commission on June 24, 2014.[7] The Plan was published for comment in the **Federal Register** on November 7, 2014, and approved by the Commission, as modified, on May 6, 2015.[8]

The Plan is designed to allow the Commission, market participants, and the public to study and assess the impact of increment conventions on the liquidity and trading of the common stock of small-capitalization companies. Each Participant is required to comply, and to enforce compliance by its member organizations, as applicable, with the provisions of the Plan.

The Plan provides for the creation of a group of Pilot Securities, which shall be placed in a control group and three separate test groups, with each subject to varying quoting and trading increments. Pilot Securities in the control group will be quoted at the current tick size increment of $0.01 per share and will trade at the currently permitted increments. Pilot Securities in the first test group will be quoted in $0.05 minimum increments but will continue to trade at any price increment that is currently permitted.[9] Pilot Securities in the second test group (“Test Group Two”) will be quoted in $0.05 minimum increments and will trade at $0.05 minimum increments subject to a midpoint exception, a retail investor order exception, and a negotiated trade exception.[10] Pilot Securities in the third test group (“Test Group Three”) will be subject to the same quoting and trading increments as Test Group Two, and also will be subject to the “Trade-at” requirement to prevent price matching by a market participant that is not displaying at the price of a Trading Center's “Best Protected Bid” or “Best Protected Offer,” unless an enumerated exception applies.[11] In addition to the exceptions provided under Test Group Two, an exception for Block Size orders and exceptions that mirror those under Rule 611 of Regulation NMS[12] will apply to the Trade-at requirement.

The Plan also requires a Trading Center[13] or a Market Maker[14] to collect and transmit certain data to its designated examining authority (“DEA”), and requires DEAs to transmit this data to the Commission. Participants that operate a Trading Center also are required under the Plan to collect certain data, which is then transmitted directly to the Commission. With respect to Trading Centers, Appendix B.I to the Plan (Market Quality Statistics) requires a Trading Center to submit to the Participant that is its DEA a variety of market quality statistics. Appendix B.II to the Plan (Market and Marketable Limit Order Data) requires a Trading Center to submit information to its DEA relating to market orders and marketable limit orders, including the time of order receipt, order type, the order size, and the National Best Bid and National Best Offer quoted price.

With respect to Market Makers, Appendix B.III requires a Participant that is a national securities exchange to collect daily Market Maker Registration statistics. Appendix B.IV requires a Participant to collect data related to Market Maker participation with respect to each Market Maker engaging in trading activity on a Trading Center operated by the Participant. Appendix C.I requires a Participant to collect data related to Market Maker profitability from each Market Maker for which it is the DEA. Appendix C.II requires the Participant, as DEA, to aggregate the Appendix C.I data, and to transmit this data to the Commission.

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[33] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78k–1.

[5] 17 CFR 242.608.

[6] *See* Letter from Brendon J. Weiss, Vice President, Intercontinental Exchange, Inc., to Secretary, Commission, dated August 25, 2014.

[7] *See* Securities Exchange Act Release No 72460 (June 24, 2014), 79 FR 36840 (June 30, 2014).

[8] *See* Securities Exchange Act Release No. 74892 (May 6, 2015), 80 FR 27513 (May 13, 2015) (“Approval Order”).

[9] *See* Section VI(B) of the Plan.

[10] *See* Section VI(C) of the Plan.

[11] *See* Section VI(D) of the Plan.

[12] 17 CFR 242.611.

[13] The Plan incorporates the definition of a “Trading Center” from Rule 600(b)(78) of Regulation NMS. Regulation NMS defines a “Trading Center” as “a national securities exchange or national securities association that operates an SRO trading facility, an alternative trading system, an exchange market maker, an OTC market maker, or any other broker or dealer that executes orders internally by trading as principal or crossing orders as agent.” *See* 17 CFR 242.600(b).

[14] The Plan defines a Market Maker as “a dealer registered with any self-regulatory organization, in accordance with the rules thereof, as (i) a market maker or (ii) a liquidity provider with an obligation to maintain continuous, two-sided trading interest.”

The Commission approved the Pilot on a two-year basis, with implementation to begin no later than May 6, 2016.[15] On November 6, 2015, the SEC exempted the Participants from implementing the pilot until October 3, 2016.[16] As set forth in Appendices B and C to the Plan, data that is reported pursuant to the appendices shall be provided for dates starting six months prior to the Pilot Period through six months after the end of the Pilot Period. Under the revised Pilot implementation date, the Pre-Pilot data collection period commenced on April 4, 2016.

On March 25, 2016, NYSE filed with the Commission a proposed rule change to adopt NYSE Rule 67(b) to implement the data collection requirements of the Plan.[17] On December 9, 2015, NYSE submitted an exemptive request to the Commission, seeking an exemption from certain data collection and reporting requirements set forth in the Plan.[18] On April 4, 2016, the Commission granted exemptive relief from complying with certain data collection and reporting requirements in the Plan.[19]

NYSE now proposes to further amend Rule 67 to modify additional data collection and reporting requirements. First, Appendix B.I.a(21) through B.I.a(27) currently requires that Trading Centers report the cumulative number of shares of cancelled orders during a specified duration of time after receipt of the order that was cancelled. NYSE and the other Participants believe that, for purposes of reporting cancelled orders, it is appropriate to categorize unexecuted Immediate or Cancel orders separately as one bucket irrespective of the duration of time after order receipt, *i.e.,* without a time increment, to better differentiate orders cancelled subsequent to entry from those where the customer's intent prior to order entry was to cancel the order if no execution could be immediately obtained. NYSE, therefore, proposes to modify Supplementary Material .30 to provide that unexecuted Immediate or Cancel orders shall be categorized separately for purposes of Appendix B.I.a(21) through B.I.a(27).

The second change relates to the reporting of daily market quality statistics pursuant to Appendix B.I. Currently, Appendix B.I sets forth categories of orders, including market orders, marketable limit orders, and inside-the-quote resting limit orders, for which daily market quality statistics must be reported. NYSE and the other Participants have determined that it is appropriate to include an order type for limit orders priced more than $0.10 away from the NBBO for purposes of Appendix B reporting. NYSE therefore proposes to amend Supplementary Material .50 to provide that limit orders priced more than $0.10 away from the NBBO shall be included as an order type for purposes of Appendix B reporting, and shall be assigned the number (22). These orders are not currently required to be reported pursuant to Appendix B, and NYSE and the other Participants believe that requiring the reporting of such orders will produce a more comprehensive data set.

The third change relates to the reporting of market quality statistics pursuant to Appendix B.I for a variety of order types, including inside-the-quote resting limit orders (12), at-the-quote resting limit orders (13), and near-the-quote resting limit orders (within $0.10 of the NBBO) (14). NYSE and the other Participants believe that it is appropriate to require Trading Centers to report all orders that fall within these categories, and not just those orders that are "resting." NYSE, therefore, proposes to amend Supplementary Material .50 to make this change.

In the fourth change, NYSE proposes to add new Supplementary Material .100 to modify the manner in which market maker participation statistics are calculated. Currently, Appendix B.IV provides that market maker participation statistics shall be calculated based on share participation, trade participation, cross-quote share (trade) participation, inside-the-quote share (trade) participation, at-the-quote share (trade) participation, and outside-the-quote share (trade) participation. NYSE and the other Participants have determined that it is appropriate to add the count of the number of Market Makers used in the calculation of share (trade) participation to each category. NYSE is therefore proposing this change as part of Supplementary Material .100. In addition, Appendix B.IV(b) and (c) currently require that, when aggregating across Market Makers, share participation and trade participation shall be calculated using the share-weighted average and trade-weighted average, respectively. NYSE and the other Participants believe that it is more appropriate to calculate share and trade participation by providing the total count of shares or trades, as applicable, rather than weighted averages, and NYSE is therefore proposing this change as part of Supplementary Material .100.

The fifth change relates to the NBBO that a Trading Center is required to use when performing certain quote-related calculations. When calculating cross-quote share (trade) participation pursuant to Appendix B.IV(d) and inside-the-quote share (trade) participation pursuant to Appendix B.IV(e), the Plan requires the Trading Center to utilize the NBBO at the time of the trade for both share and trade participation calculations. When calculating at-the-quote share (trade) participation and outside-the-quote share (trade) participation pursuant to Appendix B.IV(f) and (g), the Plan allows the Trading Center to utilize the National Best Bid or National Best Offer (NBBO) at the time of or immediately before the trade for both share and trade participation calculations. NYSE and the other Participants believe that it is appropriate to calculate all quote participation (cross-quote share (trade) participation, inside-the-quote share (trade) participation, at-the-quote share (trade) participation and outside-the-quote share (trade) participation) solely by reference to the NBBO in effect immediately prior to the trade. NYSE therefore proposes to make this change as part of Supplementary Material .100.

Finally, NYSE proposes to change the end date until which the Pre-Pilot Data Collection Securities shall be used to fulfill the Plan's data collection requirements. Currently, Supplementary Material .90 provides that Pre-Pilot Data Collection Securities are the securities designated by the Participants for purposes of the data collection requirements described in Items I, II and IV of Appendix B and Item I of Appendix C to the Plan for the period beginning six months prior to the Pilot Period and ending on the trading day immediately preceding the Pilot Period. NYSE and the other Participants believe that it is appropriate to use the Pilot

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[15] *See* Approval Order at 27533 and 27545.

[16] *See* Securities Exchange Act Release No. 76382 (November 6, 2015), 80 FR 70284 (November 13, 2015) (File No. 4–657).

[17] *See* Securities Exchange Act Release No. 77468 (March 29, 2016), 81 FR 19269 (April 4, 2016) (Immediate Effectiveness of Proposed Rule Change Adopting Requirements for the Collection and Transmission of Data Pursuant to Appendices B and C of the Regulation NMS Plan to Implement a Tick Size Pilot Program) (SR–NYSE–2016–27).

NYSE also submitted a proposed rule change to implement the quoting and trading requirements of the Plan. *See* Securities Exchange Act Release No. 77703 (April 25, 2016), 81 FR 25725 (April 29, 2016) (Order Approving SR–NYSE–2015–46).

[18] *See* Letter from Marcia E. Asquith, Senior Vice President and Corporate Secretary, FINRA, to Robert W. Errett, Deputy Secretary, Commission, dated December 9, 2015 ("Exemptive Request").

[19] *See* letter from John C. Roeser, Associate Director, Division of Trading and Markets, Commission, to Sherry Sandler, Associate General Counsel, NYSE, dated April 4, 2016.

Securities to satisfy the Plan's data collection requirements prior to the commencement of the Pilot. According, NYSE is revising Supplementary Material .90 to provide that the Pre-Pilot Data Collection Securities shall be used to satisfy the Plan's data collection requirements through thirty-one days prior to the Pilot Period, after which time the Pilot Securities shall be used for purposes of the data collection requirements.[20]

As noted in Item 2 of this filing, NYSE has filed the proposed rule change for immediate effectiveness. NYSE has requested that the SEC waive the 30-day operative period so that the proposed rule change can become operative on August 30, 2016.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[21] in general, and furthers the objectives of Section 6(b)(5) of the Act[22] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

NYSE believes that this proposal is consistent with the Act because it implements and clarifies the provisions of the Plan, and is designed to assist NYSE in meeting its regulatory obligations pursuant to the Plan. In approving the Plan, the SEC noted that the Pilot was an appropriate, data-driven test that was designed to evaluate the impact of a wider tick size on trading, liquidity, and the market quality of securities of smaller capitalization companies, and was therefore in furtherance of the purposes of the Act. NYSE believes that this proposal is in furtherance of the objectives of the Plan, as identified by the SEC, and is therefore consistent with the Act because the proposal implements and clarifies the requirements of the Plan.

B. Self-Regulatory Organization's Statement on Burden on Competition

NYSE notes that the proposed rule change implements the provisions of the Plan, and is designed to assist NYSE in meeting its regulatory obligations pursuant to the Plan. NYSE also notes that, other than the change to require use of the Pilot Securities beginning thirty days prior to the beginning of the Pilot Period, the proposed changes will only affect how NYSE and Participants that operate Trading Centers collect and report data. NYSE notes that, with respect to the change to require the use of the Pilot Securities beginning thirty days prior to the start of the Pilot Period, the proposed change reduces the number of securities on which affected members otherwise would have been required to collect data pursuant to the Plan and NYSE Rule 67. In addition, the proposed rule change applies equally to all similarly situated members. Therefore, NYSE does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[23] and Rule 19b–4(f)(6) thereunder.[24] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) by its terms, become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest.

A proposed rule change filed under Rule 19b–4(f)(6)[25] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[26] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because it will allow the Exchange to implement the proposed rules immediately thereby preventing delays in the implementation of the Plan. The Commission notes that the Plan is scheduled to start on October 3, 2016. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change to be operative upon filing with the Commission.[27]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[28] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2016–63 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

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[20] After regular trading hours on September 2, 2016, the national securities exchanges will establish which securities will be included as Pilot Securities for purposes of the Plan. NYSE and the other Participants have determined that members should use the Pilot Securities list for data collection purposes once it becomes available. Thus, the proposed rule change requires that, beginning thirty days prior to the first day of the Pilot Period—*i.e.,* September 3, 2016—NYSE and NYSE members will comply with the data collection obligations of the Plan by collecting data on the Pilot Securities. As a result, beginning on September 3, 2016, members must migrate from using NYSE's published Pre-Pilot Data Collection Security list and begin using the Pilot Securities list. September 2, 2016 will be the last day that members use the Pre-Pilot Data Collection Security list.

[21] 15 U.S.C. 78f(b).

[22] 15 U.S.C. 78f(b)(5).

[23] 15 U.S.C. 78s(b)(3)(A)(iii).

[24] 17 CFR 240.19b–4(f)(6).

[25] 17 CFR 240.19b–4(f)(6).

[26] 17 CFR 240.19b–4(f)(6)(iii).

[27] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[28] 15 U.S.C. 78s(b)(2)(B).

All submissions should refer to File Number SR–NYSE–2016–63. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2016–63 and should be submitted on or before October 7, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–22252 Filed 9–15–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78811; File No. SR–BX–2016–048]

Self-Regulatory Organizations; NASDAQ BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 4770

September 12, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 29, 2016, NASDAQ BX, Inc. ("BX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 4770 to modify certain data collection requirements of the Regulation NMS Plan to Implement a Tick Size Pilot Program.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqbx.cchwallstreet.com/*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On August 25, 2014, BX and several other self-regulatory organizations (the "Participants") filed with the Commission, pursuant to Section 11A of the Act[3] and Rule 608 of Regulation NMS thereunder,[4] the Plan to Implement a Tick Size Pilot Program (the "Plan").[5] The Participants filed the Plan to comply with an order issued by the Commission on June 24, 2014.[6] The Plan was published for comment in the **Federal Register** on November 7, 2014, and approved by the Commission, as modified, on May 6, 2015.[7]

The Plan is designed to allow the Commission, market participants, and the public to study and assess the impact of increment conventions on the liquidity and trading of the common stock of small-capitalization companies. Each Participant is required to comply, and to enforce compliance by its member organizations, as applicable, with the provisions of the Plan.

The Plan provides for the creation of a group of Pilot Securities, which shall be placed in a control group and three separate test groups, with each subject to varying quoting and trading increments. Pilot Securities in the control group will be quoted at the current tick size increment of $0.01 per share and will trade at the currently permitted increments. Pilot Securities in the first test group will be quoted in $0.05 minimum increments but will continue to trade at any price increment that is currently permitted.[8] Pilot Securities in the second test group ("Test Group Two") will be quoted in $0.05 minimum increments and will trade at $0.05 minimum increments subject to a midpoint exception, a retail investor order exception, and a negotiated trade exception.[9] Pilot Securities in the third test group ("Test Group Three") will be subject to the same quoting and trading increments as Test Group Two, and also will be subject to the "Trade-at" requirement to prevent price matching by a market participant that is not displaying at the price of a Trading Center's "Best Protected Bid" or "Best Protected Offer," unless an enumerated exception applies.[10] In addition to the exceptions provided under Test Group Two, an exception for Block Size orders and exceptions that mirror those under Rule 611 of Regulation NMS[11] will apply to the Trade-at requirement.

The Plan also requires a Trading Center[12] or a Market Maker[13] to collect and transmit certain data to its designated examining authority ("DEA"), and requires DEAs to transmit this data to the Commission. Participants that operate a Trading Center also are required under the Plan to collect certain data, which is then transmitted directly to the Commission. With respect to Trading Centers, Appendix B.I to the Plan (Market Quality Statistics) requires a Trading Center to submit to the Participant that is its DEA a variety of market quality statistics. Appendix B.II to the Plan (Market and Marketable Limit Order Data) requires a Trading Center to submit information to its DEA relating to market orders and marketable limit orders, including the time of order receipt, order type, the order size, and the National Best Bid or National Best Offer ("NBBO") quoted price.

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[29] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78k–1.

[4] 17 CFR 242.608.

[5] *See* Letter from Brendon J. Weiss, Vice President, Intercontinental Exchange, Inc., to Secretary, Commission, dated August 25, 2014.

[6] *See* Securities Exchange Act Release No 72460 (June 24, 2014), 79 FR 36840 (June 30, 2014).

[7] *See* Securities Exchange Act Release No. 74892 (May 6, 2015), 80 FR 27513 (May 13, 2015) ("Approval Order").

[8] *See* Section VI(B) of the Plan.

[9] *See* Section VI(C) of the Plan.

[10] *See* Section VI(D) of the Plan.

[11] 17 CFR 242.611.

[12] The Plan incorporates the definition of a "Trading Center" from Rule 600(b)(78) of Regulation NMS. Regulation NMS defines a "Trading Center" as "a national securities exchange or national securities association that operates an SRO trading facility, an alternative trading system, an exchange market maker, an OTC market maker, or any other broker or dealer that executes orders internally by trading as principal or crossing orders as agent." *See* 17 CFR 242.600(b).

[13] The Plan defines a Market Maker as "a dealer registered with any self-regulatory organization, in accordance with the rules thereof, as (i) a market

With respect to Market Makers, Appendix B.III requires a Participant that is a national securities exchange to collect daily Market Maker Registration statistics. Appendix B.IV requires a Participant to collect data related to Market Maker participation with respect to each Market Maker engaging in trading activity on a Trading Center operated by the Participant. Appendix C.I requires a Participant to collect data related to Market Maker profitability from each Market Maker for which it is the DEA.

Appendix C.II requires the Participant, as DEA, to aggregate the Appendix C.I data, and to transmit this data to the Commission.

The Commission approved the Pilot on a two-year basis, with implementation to begin no later than May 6, 2016.[14] On November 6, 2015, the SEC exempted the Participants from implementing the Pilot until October 3, 2016.[15] As set forth in Appendices B and C to the Plan, data that is reported pursuant to the appendices shall be provided for dates starting six months prior to the Pilot Period through six months after the end of the Pilot Period. Under the revised Pilot implementation date, the Pre-Pilot data collection period commenced on April 4, 2016.

On December 9, 2015, FINRA, on behalf of the Plan Participants, submitted an exemptive request to the Commission, seeking an exemption from certain data collection and reporting requirements set forth in the Plan.[16] On February 17, 2016, the Commission granted Participants exemptive relief from complying with certain data collection and reporting requirements in the Plan.[17] On March 23, 2016, the Exchange filed with the Commission a proposed rule change to adopt Rule 4770 to implement the data collection requirements of the Plan, which was effective on April 4, 2016.[18]

The Exchange now proposes to further amend Rule 4770 to modify additional data collection and reporting requirements.[19] First, Appendix B.I.a(21) through B.I.a(27) currently requires that Trading Centers report the cumulative number of shares of cancelled orders during a specified duration of time after receipt of the order that was cancelled. The Exchange and the other Participants believe that, for purposes of reporting cancelled orders, it is appropriate to categorize unexecuted Immediate or Cancel orders separately as one bucket irrespective of the duration of time after order receipt, *i.e.,* without a time increment, to better differentiate orders cancelled subsequent to entry from those where the customer's intent prior to order entry was to cancel the order if no execution could be immediately obtained. The Exchange, therefore, proposes to modify Commentary .04 to provide that unexecuted Immediate or Cancel orders shall be categorized separately for purposes of Appendix B.I.a(21) through B.I.a(27).

The second change relates to the reporting of daily market quality statistics pursuant to Appendix B.I. Currently, Appendix B.I sets forth categories of orders, including market orders, marketable limit orders, and inside-the-quote resting limit orders, for which daily market quality statistics must be reported. The Exchange and the other Participants have determined that it is appropriate to include an order type for limit orders priced more than $0.10 away from the NBBO for purposes of Appendix B reporting. The Exchange therefore proposes to amend Commentary .06 to provide that limit orders priced more than $0.10 away from the NBBO shall be included as an order type for purposes of Appendix B reporting, and shall be assigned the number (22). These orders are not currently required to be reported pursuant to Appendix B, and the Exchange and the other Participants believe that requiring the reporting of such orders will produce a more comprehensive data set.

The third change relates to the reporting of market quality statistics pursuant to Appendix B.I for a variety of order types, including inside-the-quote resting limit orders (12), at-the-quote resting limit orders (13), and near-the-quote resting limit orders (within $0.10 of the NBBO) (14). The Exchange and the other Participants believe that it is appropriate to require Trading Centers to report all orders that fall within these categories, and not just those orders that are "resting." The Exchange, therefore, proposes to amend Commentary .06 to make this change.

In the fourth change, the Exchange proposes to add new Commentary .09 to modify the manner in which market maker participation statistics are calculated. Currently, Appendix B.IV provides that market maker participation statistics shall be calculated based on share participation, trade participation, cross-quote share (trade) participation, inside-the-quote share (trade) participation, at-the-quote share (trade) participation, and outside-the-quote share (trade) participation. The Exchange and the other Participants have determined that it is appropriate to add the count of the number of Market Makers used in the calculation of share (trade) participation to each category. The Exchange is therefore proposing this change as part of Commentary .09. In addition, Appendix B.IV(b) and (c) currently require that, when aggregating across Market Makers, share participation and trade participation shall be calculated using the share-weighted average and trade-weighted average, respectively. The Exchange and the other Participants believe that it is more appropriate to calculate share and trade participation by providing the total count of shares or trades, as applicable, rather than weighted averages, and the Exchange is therefore proposing this change as part of Commentary .09.

The fifth change relates to the NBBO that a Trading Center is required to use when performing certain quote-related calculations. When calculating cross-quote share (trade) participation pursuant to Appendix B.IV(d) and inside-the-quote share (trade) participation pursuant to Appendix

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maker or (ii) a liquidity provider with an obligation to maintain continuous, two-sided trading interest."

[14] *See* Approval Order at 27533 and 27545.

[15] *See* Securities Exchange Act Release No. 76382 (November 6, 2015), 80 FR 70284 (November 13, 2015) (File No. 4–657).

[16] *See* Letter from Marcia E. Asquith, Senior Vice President and Corporate Secretary, FINRA, to Robert W. Errett, Deputy Secretary, Commission, dated December 9, 2015 ("Exemptive Request").

[17] *See* Letter from David S. Shillman, Associate Director, Division of Trading and Markets, Commission, to Marcia E. Asquith, Senior Vice President and Corporate Secretary, FINRA, dated February 17, 2016.

[18] *See* Securities Exchange Act Release No. 77457 (March 28, 2016), 81 FR 18913 (April 1, 2016) (SR–BX–2016–019).

[19] In connection with this proposed rule change and others made by Participants, FINRA intends to file an exemptive request on behalf of Participants seeking relief from certain of the Plan's data collection requirements.

B.IV(e), the Plan requires the Trading Center to utilize the NBBO at the time of the trade for both share and trade participation calculations. When calculating at-the-quote share (trade) participation and outside-the quote share (trade) participation pursuant to Appendix B.IV(f) and (g), the Plan allows the Trading Center to utilize the NBBO at the time of or immediately before the trade for both share and trade participation calculations. The Exchange and the other Participants believe that it is appropriate to calculate all quote participation (cross-quote share (trade) participation, inside-the-quote share (trade) participation, at-the-quote share (trade) participation and outside-the-quote share (trade) participation) solely by reference to the NBBO in effect immediately prior to the trade. The Exchange, therefore, proposes to make this change as part of Commentary .09.

Finally, the Exchange proposes to change the end date until which the Pre-Pilot Data Collection Securities shall be used to fulfill the Plan's data collection requirements. Currently, Commentary .10 provides that Pre-Pilot Data Collection Securities are the securities designated by the Participants for purposes of the data collection requirements described in Items I, II and IV of Appendix B and Item I of Appendix C to the Plan for the period beginning six months prior to the Pilot Period and ending on the trading day immediately preceding the Pilot Period. The Exchange and the other Participants believe that it is appropriate to use the Pilot Securities to satisfy the Plan's data collection requirements prior to the commencement of the Pilot. Accordingly, the Exchange is revising Commentary .10 (which will be re-numbered as Commentary .11) to provide that the Pre-Pilot Data Collection Securities shall be used to satisfy the Plan's data collection requirements through thirty-one days prior to the Pilot Period, after which time the Pilot Securities shall be used for purposes of the data collection requirements.[20] As noted in Item 2 of this filing, the Exchange has filed the proposed rule change for immediate effectiveness. The Exchange has requested that the SEC waive the 30-day operative period so that the proposed rule change can become operative on August 30, 2016.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[21] in general, and furthers the objectives of Section 6(b)(5) of the Act,[22] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, and Section 6(b)(8) of the Act,[23] which requires that the Exchange not impose any burden on competition that is not necessary or appropriate.

The Exchange believes that this proposal is consistent with the Act because it implements and clarifies the provisions of the Plan, and is designed to assist the Exchange in meeting its regulatory obligations pursuant to the Plan. In approving the Plan, the SEC noted that the Pilot was an appropriate, data-driven test that was designed to evaluate the impact of a wider tick size on trading, liquidity, and the market quality of securities of smaller capitalization companies, and was therefore in furtherance of the purposes of the Act. The Exchange believes that this proposal is in furtherance of the objectives of the Plan, as identified by the SEC, and is therefore consistent with the Act because the proposal implements and clarifies the requirements of the Plan.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that the proposed rule change implements the provisions of the Plan, and is designed to assist the Exchange in meeting its regulatory obligations pursuant to the Plan. The Exchange also notes that, other than the change to require use of the Pilot Securities beginning thirty days prior to the beginning of the Pilot Period, the proposed changes will not affect the data collection and reporting requirements for members that operate Trading Centers; the proposed changes will only affect how the Exchange and Participants that operate Trading Centers collect and report data. The Exchange notes that, with respect to the change to require the use of the Pilot Securities beginning thirty days prior to the start of the Pilot Period, the proposed change reduces the number of securities on which affected members otherwise would have been required to collect data pursuant to the Plan and Rule 4770. In addition, the proposed rule change applies equally to all similarly situated members. Therefore, the Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[24] and Rule 19b–4(f)(6)[25] thereunder because the proposal does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) by its terms, become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest.

A proposed rule change filed under Rule 19b–4(f)(6)[26] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[27] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that so that the proposed rule change can become operative on August 30, 2016.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because it will allow the Exchange to implement the proposed rules immediately thereby preventing delays in the implementation of the Plan. The Commission notes that the Plan is scheduled to start on October 3, 2016. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change to be operative upon filing with the Commission.[28]

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[20] After regular trading hours on September 2, 2016, the national securities exchanges will establish which securities will be included as Pilot Securities for purposes of the Plan. The Exchange and the other Participants have determined that members should use the Pilot Securities list for data collection purposes once it becomes available. Thus, the proposed rule change requires that, beginning thirty days prior to the first day of the Pilot Period—*i.e.,* September 3, 2016—The Exchange and Exchange members will comply with the data collection obligations of the Plan by collecting data on the Pilot Securities. As a result, beginning on September 3, 2016, members must migrate from using the Exchange's published Pre-Pilot Data Collection Security list and begin using the Pilot Securities list. September 2, 2016 will be the last day that members use the Pre-Pilot Data Collection Security list.

[21] 15 U.S.C. 78f(b).

[22] 15 U.S.C. 78f(b)(5).

[23] 15 U.S.C. 78f(b)(8).

[24] 15 U.S.C. 78s(b)(3)(A).

[25] 17 CFR 240.19b–4(f)(6).

[26] 17 CFR 240.19b–4(f)(6).

[27] 17 CFR 240.19b–4(f)(6)(iii).

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.[29]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2016–048 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2016–048. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2016–048 and should be submitted on or before October 7, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–22250 Filed 9–15–16; 8:45 am]

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[28] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[29] 15 U.S.C. 78s(b)(3)(C).

[30] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78818; File No. SR–ICC–2016–012]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule Change To Provide for the Clearance of Additional Credit Default Swap Contracts

September 12, 2016.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder[2] notice is hereby given that on August 29, 2016, ICE Clear Credit LLC ("ICC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by ICC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed rule change is to revise the ICC Rulebook (the "Rules") to provide for the clearance of additional Standard Emerging Market Sovereign CDS contracts (collectively, "EM Contracts"), 2003 ISDA Definitions of Standard Western European Sovereign CDS contracts (collectively, "SWES Contracts"), and an additional Asia/Pacific Sovereign CDS contract (the "Asia/Pacific Contract").

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. ICC has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of these statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to adopt rules that will provide the basis for ICC to clear additional credit default swap contracts. ICC believes the addition of these contracts will benefit the market for credit default swaps by providing market participants the benefits of clearing, including reduction in counterparty risk and safeguarding of margin assets pursuant to clearing house rules.

ICC proposes amending subchapter 26D of its Rules to provide for the clearance of additional EM Contracts, specifically the Republic of Panama, Abu Dhabi, Dubai, the State of Israel and the State of Qatar. ICC plans to offer these additional EM Contracts on the 2003 and 2014 ISDA Credit Derivatives Definitions.

These additional EM Contracts have terms consistent with the other EM Contracts approved for clearing at ICC and governed by subchapter 26D of the Rules. Minor revisions to Subchapter 26D (Standard Emerging Market Sovereign ("SES") Single Name) are made to provide for clearing the additional EM Contracts. Specifically, in Rule 26D–102 (Definitions), "Eligible SES Reference Entities" is modified to include the Republic of Panama, Abu Dhabi, Dubai, the State of Israel and the State of Qatar in the list of specific Eligible SES Reference Entities to be cleared by ICC.

Additionally, ICC proposes amending subchapter 26I of its Rules to provide for the clearance of 2003 ISDA Definitions of SWES Contracts. ICC currently clears the 2014 ISDA Definitions of ten SWES Contracts, namely the Republic of Ireland, the Italian Republic, the Portuguese Republic, the Kingdom of Spain, the Kingdom of Belgium, the Republic of Austria, the Kingdom of the Netherlands, the Federal Republic of Germany, the French Republic, and the United Kingdom of Great Britain and Northern Ireland. The proposed rule changes to subchapter 26I will allow ICC to offer clearing for the 2003 ISDA Definitions of these SWES Contracts.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Minor revisions to subchapter 26I (Standard Western European (''SWES'') Single Name) are made to provide for clearing the 2003 ISDA Definitions of SWES Contracts. Specifically, in Rule 26I–102 (Definitions), the definitions of ''Eligible SWES Reference Obligations'', ''List of Eligible SWES Reference Entities'' and ''SWES Contract Reference Obligations'' are updated to distinguish between the 2003- and 2014-Type CDS Contracts, and the corresponding Applicable Credit Derivatives Definitions.[3] Rule 26I–309 (Acceptance of SWES Contracts by ICE Clear Credit) is revised in part (c) to note that a CDS Participant may not submit a Trade for clearance as a SWES contract, and any such Trade shall not be a Confirming Trade, if the *acceptance* would be at a time when the CDS Participant (or any Non-Participant Party for whom such CDS Participant is acting) is, or is an Affiliate of, the Eligible SWES Reference Entity for such SWES Contract or is subject to an agreement under which it is reasonably likely that the CDS Participant (or any such Non-Participant Party) will become, or will become an Affiliate of, the Eligible SWES Reference Entity for such SWES Contract. Rule 26I–309 is also revised in part (e) to address and distinguish between relevant successor or other events under both 2003- and 2014-Type CDS Contracts, and the corresponding Applicable Credit Derivatives Definitions.

Rule 26I–315 (Terms of the Cleared SWES Contract) is revised to provide reference to provisions of the proper ISDA Definitions, and corresponding changes to provision numbering are made as necessary. Rule 26I–315(h) is revised to refer to the Applicable Credit Derivatives Definitions and eligible Seniority Level, as appropriate.

Defined terms in Rule 26I–316 (Physical Settlement Matrix Updates) are updated to refer specifically to SWES contracts. Rule 26I–616 (Contract Modification) is revised to note that it shall not constitute a Contract Modification if the Board (or its designee) updates the List of Eligible SWES Reference Entities (and modifies the terms and conditions of related SWES Contracts) to give effect to determinations of Succession Events.

Finally, ICC proposes amending subchapter 26L of its rules to provide for the clearance of an additional Asia/Pacific Contract, namely the Kingdom of Thailand. ICC plans to offer this contract on the 2003 and 2014 ISDA Credit Derivatives Definitions.

The additional Asia/Pacific Contract has terms consistent with the other Asia/Pacific Contracts approved for clearing at ICC and governed by subchapter 26L of the Rules. Minor revisions to subchapter 26L (Asia/Pacific Sovereign (''SAS'') Single Name) are made to provide for clearing the additional Asia/Pacific Contract. Specifically, in Rule 26L–102 (Definitions), ''Eligible SAS Reference Entities'' is modified to include the Kingdom of Thailand in the list of specific Eligible SAS Reference Entities to be cleared by ICC.

Section 17A(b)(3)(F) of the Act[4] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions and to comply with the provisions of the Act and the rules and regulations thereunder. The additional EM Contracts, Asia/Pacific Contract and the 2003 ISDA Definitions of SWES Contracts proposed for clearing are similar to the EM, SWES, and Asia/Pacific Contracts currently cleared by ICC, and will be cleared pursuant to ICC's existing clearing arrangements and related financial safeguards, protections and risk management procedures. Clearing of the additional EM Contracts, Asia/Pacific Contract and 2003 ISDA Definitions of SWES Contracts will allow market participants an increased ability to manage risk and ensure the safeguarding of margin assets pursuant to clearing house rules. ICC believes that acceptance of the new EM Contracts, Asia/Pacific Contract and 2003 ISDA Definitions of SWES Contracts, on the terms and conditions set out in the Rules, is consistent with the prompt and accurate clearance of and settlement of securities transactions and derivative agreements, contracts and transactions cleared by ICC, the safeguarding of securities and funds in the custody or control of ICC, and the protection of investors and the public interest, within the meaning of Section 17A(b)(3)(F) of the Act.[5]

Clearing of the additional EM Contracts, Asia/Pacific Contract and 2003 ISDA Definitions of SWES Contracts will also satisfy the requirements of Rule 17Ad–22.[6] In particular, in terms of financial resources, ICC will apply its existing initial margin methodology to the additional contracts. ICC believes that this model will provide sufficient initial margin requirements to cover its credit exposure to its clearing members from clearing such contracts, consistent with the requirements of Rule 17Ad–22(b)(2).[7] In addition, ICC believes its Guaranty Fund, under its existing methodology, will, together with the required initial margin, provide sufficient financial resources to support the clearing of the additional contracts consistent with the requirements of Rule 17Ad–22(b)(3).[8] ICC also believes that its existing operational and managerial resources will be sufficient for clearing of the additional contracts, consistent with the requirements of Rule 17Ad–22(d)(4),[9] as the new contracts are substantially the same from an operational perspective as existing contracts. Similarly, ICC will use its existing settlement procedures and account structures for the new contracts, consistent with the requirements of Rule 17Ad–22(d)(5), (12) and (15)[10] as to the finality and accuracy of its daily settlement process and avoidance of the risk to ICC of settlement failures. ICC determined to accept the additional EM Contracts, Asia/Pacific Contract and 2003 ISDA Definitions of SWES Contracts for clearing in accordance with its governance process, which included review of the contracts and related risk management considerations by the ICC Risk Committee and approval by its Board. These governance arrangements are consistent with the requirements of Rule 17Ad–22(d)(8).[11] Finally, ICC will apply its existing default management policies and procedures for the additional EM Contracts, Asia/Pacific Contract and 2003 ISDA Definitions of SWES Contracts. ICC believes that these procedures allow for it to take timely action to contain losses and liquidity pressures and to continue meeting its obligations in the event of clearing member insolvencies or defaults in respect of the additional single names, in accordance with Rule 17Ad–22(d)(11).[12]

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[3] As defined in Rule 20–102 (Applicable Credit Derivatives Definitions).

[4] 15 U.S.C. 78q–1(b)(3)(F).

[5] 15 U.S.C. 78q–1(b)(3)(F).

[6] 17 CFR 240.17Ad–22.

[7] 17 CFR 240.17Ad–22(b)(2).

[8] 17 CFR 240.17Ad–22(b)(3).

[9] 17 CFR 240.17Ad–22(d)(4).

[10] 17 CFR 240.17Ad–22(d)(5), (12) and (15).

[11] 17 CFR 240.17Ad–22(d)(8).

B. Self-Regulatory Organization's Statement on Burden on Competition

The additional EM Contracts, Asia/Pacific Contract and 2003 ISDA Definitions of SWES Contracts will be available to all ICC participants for clearing. The clearing of these additional EM Contracts, Asia/Pacific Contract and 2003 ISDA Definitions of SWES Contracts by ICC does not preclude the offering of the additional EM Contracts, Asia/Pacific Contract and 2003 ISDA Definitions of SWES Contracts for clearing by other market participants. Accordingly, ICC does not believe that clearance of the additional EM Contracts, Asia/Pacific Contract and 2003 ISDA Definitions of SWES Contracts will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. ICC will notify the Commission of any written comments received by ICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–ICC–2016–012 on the subject line.

Paper Comments

Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ICC–2016–012. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Credit and on ICE Clear Credit's Web site at *https://www.theice.com/clear-credit/regulation*.

All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICC–2016–012 and should be submitted on or before October 7, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–22257 Filed 9–15–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78815; File No. SR–Phlx–2016–90]

Self-Regulatory Organizations; NASDAQ PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 3317

September 12, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 29, 2016, NASDAQ PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 3317 to modify certain data collection requirements of the Regulation NMS Plan to Implement a Tick Size Pilot Program.

The Exchange requests that the Commission waive the 30-day operative delay period contained in Exchange Act Rule 19b–4(f)(6)(iii).[3]

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqphlx.cchwallstreet.com/*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

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[12] 17 CFR 240.17Ad–22(d)(11).

[13] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6)(iii).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On August 25, 2014, Phlx and several other self-regulatory organizations (the "Participants") filed with the Commission, pursuant to Section 11A of the Act[4] and Rule 608 of Regulation NMS thereunder,[5] the Plan to Implement a Tick Size Pilot Program (the "Plan").[6] The Participants filed the Plan to comply with an order issued by the Commission on June 24, 2014.[7] The Plan was published for comment in the **Federal Register** on November 7, 2014, and approved by the Commission, as modified, on May 6, 2015.[8]

The Plan is designed to allow the Commission, market participants, and the public to study and assess the impact of increment conventions on the liquidity and trading of the common stock of small-capitalization companies. Each Participant is required to comply, and to enforce compliance by its member organizations, as applicable, with the provisions of the Plan.

The Plan provides for the creation of a group of Pilot Securities, which shall be placed in a control group and three separate test groups, with each subject to varying quoting and trading increments. Pilot Securities in the control group will be quoted at the current tick size increment of $0.01 per share and will trade at the currently permitted increments. Pilot Securities in the first test group will be quoted in $0.05 minimum increments but will continue to trade at any price increment that is currently permitted.[9] Pilot Securities in the second test group ("Test Group Two") will be quoted in $0.05 minimum increments and will trade at $0.05 minimum increments subject to a midpoint exception, a retail investor order exception, and a negotiated trade exception.[10] Pilot Securities in the third test group ("Test Group Three") will be subject to the same quoting and trading increments as Test Group Two, and also will be subject to the "Trade-at" requirement to prevent price matching by a market participant that is not displaying at the price of a Trading Center's "Best Protected Bid" or "Best Protected Offer," unless an enumerated exception applies.[11] In addition to the exceptions provided under Test Group Two, an exception for Block Size orders and exceptions that mirror those under Rule 611 of Regulation NMS[12] will apply to the Trade-at requirement.

The Plan also requires a Trading Center[13] or a Market Maker[14] to collect and transmit certain data to its designated examining authority ("DEA"), and requires DEAs to transmit this data to the Commission. Participants that operate a Trading Center also are required under the Plan to collect certain data, which is then transmitted directly to the Commission. With respect to Trading Centers, Appendix B.I to the Plan (Market Quality Statistics) requires a Trading Center to submit to the Participant that is its DEA a variety of market quality statistics. Appendix B.II to the Plan (Market and Marketable Limit Order Data) requires a Trading Center to submit information to its DEA relating to market orders and marketable limit orders, including the time of order receipt, order type, the order size, and the National Best Bid or National Best Offer ("NBBO") quoted price.

With respect to Market Makers, Appendix B.III requires a Participant that is a national securities exchange to collect daily Market Maker Registration statistics. Appendix B.IV requires a Participant to collect data related to Market Maker participation with respect to each Market Maker engaging in trading activity on a Trading Center operated by the Participant. Appendix C.I requires a Participant to collect data related to Market Maker profitability from each Market Maker for which it is the DEA.

Appendix C.II requires the Participant, as DEA, to aggregate the Appendix C.I data, and to transmit this data to the Commission.

The Commission approved the Pilot on a two-year basis, with implementation to begin no later than May 6, 2016.[15] On November 6, 2015, the SEC exempted the Participants from implementing the Pilot until October 3, 2016.[16] As set forth in Appendices B and C to the Plan, data that is reported pursuant to the appendices shall be provided for dates starting six months prior to the Pilot Period through six months after the end of the Pilot Period. Under the revised Pilot implementation date, the Pre-Pilot data collection period commenced on April 4, 2016.

On December 9, 2015, FINRA, on behalf of the Plan Participants, submitted an exemptive request to the Commission, seeking an exemption from certain data collection and reporting requirements set forth in the Plan.[17] On February 17, 2016, the Commission granted Participants exemptive relief from complying with certain data collection and reporting requirements in the Plan.[18] On March 23, 2016, the Exchange filed with the Commission a proposed rule change to adopt Rule 3317 to implement the data collection requirements of the Plan, which was effective on April 4, 2016.[19]

The Exchange now proposes to further amend Rule 3317 to modify additional data collection and reporting requirements.[20] First, Appendix B.I.a(21) through B.I.a(27) currently requires that Trading Centers report the cumulative number of shares of cancelled orders during a specified duration of time after receipt of the order that was cancelled. The Exchange and the other Participants believe that, for purposes of reporting cancelled orders, it is appropriate to categorize unexecuted Immediate or Cancel orders separately as one bucket irrespective of the duration of time after order receipt, *i.e.,* without a time increment, to better differentiate orders cancelled subsequent to entry from those where the customer's intent prior to order entry was to cancel the order if no execution could be immediately obtained. The Exchange, therefore, proposes to modify Commentary .04 to provide that unexecuted Immediate or Cancel orders shall be categorized separately for purposes of Appendix B.I.a(21) through B.I.a(27).

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[4] 15 U.S.C. 78k–1.

[5] 17 CFR 242.608.

[6] *See* Letter from Brendon J. Weiss, Vice President, Intercontinental Exchange, Inc., to Secretary, Commission, dated August 25, 2014.

[7] *See* Securities Exchange Act Release No. 72460 (June 24, 2014), 79 FR 36840 (June 30, 2014).

[8] *See* Securities Exchange Act Release No. 74892 (May 6, 2015), 80 FR 27513 (May 13, 2015) ("Approval Order").

[9] *See* Section VI(B) of the Plan.

[10] *See* Section VI(C) of the Plan.

[11] *See* Section VI(D) of the Plan.

[12] 17 CFR 242.611.

[13] The Plan incorporates the definition of a "Trading Center" from Rule 600(b)(78) of Regulation NMS. Regulation NMS defines a "Trading Center" as "a national securities exchange or national securities association that operates an SRO trading facility, an alternative trading system, an exchange market maker, an OTC market maker, or any other broker or dealer that executes orders internally by trading as principal or crossing orders as agent." *See* 17 CFR 242.600(b).

[14] The Plan defines a Market Maker as "a dealer registered with any self-regulatory organization, in accordance with the rules thereof, as (i) a market maker or (ii) a liquidity provider with an obligation to maintain continuous, two-sided trading interest."

[15] *See* Approval Order at 27533 and 27545.

[16] *See* Securities Exchange Act Release No. 76382 (November 6, 2015), 80 FR 70284 (November 13, 2015) (File No. 4–657).

[17] *See* Letter from Marcia E. Asquith, Senior Vice President and Corporate Secretary, FINRA, to Robert W. Errett, Deputy Secretary, Commission, dated December 9, 2015 ("Exemptive Request").

[18] *See* Letter from David S. Shillman, Associate Director, Division of Trading and Markets, Commission, to Marcia E. Asquith, Senior Vice President and Corporate Secretary, FINRA, dated February 17, 2016.

[19] *See* Securities Exchange Act Release No. 77458 (March 28, 2016), 81 FR 18919 (April 1, 2016) (SR–Phlx–2016–39).

[20] In connection with this proposed rule change and others made by Participants, FINRA intends to file an exemptive request on behalf of Participants seeking relief from certain of the Plan's data collection requirements.

The second change relates to the reporting of daily market quality statistics pursuant to Appendix B.I. Currently, Appendix B.I sets forth categories of orders, including market orders, marketable limit orders, and inside-the-quote resting limit orders, for which daily market quality statistics must be reported. The Exchange and the other Participants have determined that it is appropriate to include an order type for limit orders priced more than $0.10 away from the NBBO for purposes of Appendix B reporting. The Exchange therefore proposes to amend Commentary .06 to provide that limit orders priced more than $0.10 away from the NBBO shall be included as an order type for purposes of Appendix B reporting, and shall be assigned the number (22). These orders are not currently required to be reported pursuant to Appendix B, and the Exchange and the other Participants believe that requiring the reporting of such orders will produce a more comprehensive data set.

The third change relates to the reporting of market quality statistics pursuant to Appendix B.I for a variety of order types, including inside-the-quote resting limit orders (12), at-the-quote resting limit orders (13), and near-the-quote resting limit orders (within $0.10 of the NBBO) (14). The Exchange and the other Participants believe that it is appropriate to require Trading Centers to report all orders that fall within these categories, and not just those orders that are "resting." The Exchange, therefore, proposes to amend Commentary .06 to make this change.

In the fourth change, the Exchange proposes to add new Commentary .09 to modify the manner in which market maker participation statistics are calculated. Currently, Appendix B.IV provides that market maker participation statistics shall be calculated based on share participation, trade participation, cross-quote share (trade) participation, inside-the-quote share (trade) participation, at-the-quote share (trade) participation, and outside-the-quote share (trade) participation. The Exchange and the other Participants have determined that it is appropriate to add the count of the number of Market Makers used in the calculation of share (trade) participation to each category. The Exchange is therefore proposing this change as part of Commentary .09.

In addition, Appendix B.IV(b) and (c) currently require that, when aggregating across Market Makers, share participation and trade participation shall be calculated using the share-weighted average and trade-weighted average, respectively. The Exchange and the other Participants believe that it is more appropriate to calculate share and trade participation by providing the total count of shares or trades, as applicable, rather than weighted averages, and the Exchange is therefore proposing this change as part of Commentary .09.

The fifth change relates to the NBBO that a Trading Center is required to use when performing certain quote-related calculations. When calculating cross-quote share (trade) participation pursuant to Appendix B.IV(d) and inside-the-quote share (trade) participation pursuant to Appendix B.IV(e), the Plan requires the Trading Center to utilize the NBBO at the time of the trade for both share and trade participation calculations. When calculating at-the-quote share (trade) participation and outside-the quote share (trade) participation pursuant to Appendix B.IV(f) and (g), the Plan allows the Trading Center to utilize the NBBO at the time of or immediately before the trade for both share and trade participation calculations. The Exchange and the other Participants believe that it is appropriate to calculate all quote participation (cross-quote share (trade) participation, inside-the-quote share (trade) participation, at-the-quote share (trade) participation and outside-the-quote share (trade) participation) solely by reference to the NBBO in effect immediately prior to the trade. The Exchange, therefore, proposes to make this change as part of Commentary .09.

Finally, the Exchange proposes to change the end date until which the Pre-Pilot Data Collection Securities shall be used to fulfill the Plan's data collection requirements. Currently, Commentary .10 provides that Pre-Pilot Data Collection Securities are the securities designated by the Participants for purposes of the data collection requirements described in Items I, II and IV of Appendix B and Item I of Appendix C to the Plan for the period beginning six months prior to the Pilot Period and ending on the trading day immediately preceding the Pilot Period. The Exchange and the other Participants believe that it is appropriate to use the Pilot Securities to satisfy the Plan's data collection requirements prior to the commencement of the Pilot. Accordingly, the Exchange is revising Commentary .10 (which will be re-numbered as Commentary .11) to provide that the Pre-Pilot Data Collection Securities shall be used to satisfy the Plan's data collection requirements through thirty-one days prior to the Pilot Period, after which time the Pilot Securities shall be used for purposes of the data collection requirements.[21] As noted in Item 2 of this filing, the Exchange has filed the proposed rule change for immediate effectiveness. The Exchange has requested that the SEC waive the 30-day operative period so that the proposed rule change can become operative on August 30, 2016.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[22] in general, and furthers the objectives of Section 6(b)(5) of the Act,[23] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, and Section 6(b)(8) of the Act,[24] which requires that the Exchange not impose any burden on competition that is not necessary or appropriate.

The Exchange believes that this proposal is consistent with the Act because it implements and clarifies the provisions of the Plan, and is designed to assist the Exchange in meeting its regulatory obligations pursuant to the Plan. In approving the Plan, the SEC noted that the Pilot was an appropriate, data-driven test that was designed to evaluate the impact of a wider tick size on trading, liquidity, and the market quality of securities of smaller capitalization companies, and was therefore in furtherance of the purposes of the Act. The Exchange believes that this proposal is in furtherance of the objectives of the Plan, as identified by the SEC, and is therefore consistent with the Act because the proposal implements and clarifies the requirements of the Plan.

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[21] After regular trading hours on September 2, 2016, the national securities exchanges will establish which securities will be included as Pilot Securities for purposes of the Plan. The Exchange and the other Participants have determined that members should use the Pilot Securities list for data collection purposes once it becomes available. Thus, the proposed rule change requires that, beginning thirty days prior to the first day of the Pilot Period—*i.e.,* September 3, 2016—The Exchange and Exchange members will comply with the data collection obligations of the Plan by collecting data on the Pilot Securities. As a result, beginning on September 3, 2016, members must migrate from using the Exchange's published Pre-Pilot Data Collection Security list and begin using the Pilot Securities list. September 2, 2016 will be the last day that members use the Pre-Pilot Data Collection Security list.

[22] 15 U.S.C. 78f(b).

[23] 15 U.S.C. 78f(b)(5).

[24] 15 U.S.C. 78f(b)(8).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that the proposed rule change implements the provisions of the Plan, and is designed to assist the Exchange in meeting its regulatory obligations pursuant to the Plan. The Exchange also notes that, other than the change to require use of the Pilot Securities beginning thirty days prior to the beginning of the Pilot Period, the proposed changes will not affect the data collection and reporting requirements for members that operate Trading Centers; the proposed changes will only affect how the Exchange and Participants that operate Trading Centers collect and report data. The Exchange notes that, with respect to the change to require the use of the Pilot Securities beginning thirty days prior to the start of the Pilot Period, the proposed change reduces the number of securities on which affected members otherwise would have been required to collect data pursuant to the Plan and Rule 3317. In addition, the proposed rule change applies equally to all similarly situated members. Therefore, the Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[25] and Rule 19b–4(f)(6)[26] thereunder because the proposal does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) by its terms, become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest.

A proposed rule change filed under Rule 19b–4(f)(6)[27] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[28] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that so that the proposed rule change can become operative on August 30, 2016.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because it will allow the Exchange to implement the proposed rules immediately thereby preventing delays in the implementation of the Plan. The Commission notes that the Plan is scheduled to start on October 3, 2016. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposed rule change to be operative upon filing with the Commission.[29]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.[30]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2016–90 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2016–90. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2016–90 and should be submitted on or before October 7, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–22254 Filed 9–15–16; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14849 and #14850]

Indiana Disaster #IN–00059

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Indiana dated 09/08/2016.

Incident: Tornadoes and High Winds.
Incident Period: 08/24/2016.
Effective Date: 09/08/2016.

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[25] 15 U.S.C. 78s(b)(3)(A).

[26] 17 CFR 240.19b–4(f)(6).

[27] 17 CFR 240.19b–4(f)(6).

[28] 17 CFR 240.19b–4(f)(6)(iii).

[29] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[30] 15 U.S.C. 78s(b)(3)(C).

[31] 17 CFR 200.30–3(a)(12).

Physical Loan Application Deadline Date: 11/07/2016.

Economic Injury (EIDL) Loan Application Deadline Date: 06/08/2017.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Howard
Contiguous Counties:
Indiana:
Carroll, Cass, Clinton, Grant, Miami, Tipton

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.125
Homeowners Without Credit Available Elsewhere	1.563
Businesses With Credit Available Elsewhere	6.250
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere	2.625
Non-Profit Organizations Without Credit Available Elsewhere	2.625
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	2.625

The number assigned to this disaster for physical damage is 14849 C and for economic injury is 14850 0.

The State which received an EIDL Declaration # is Indiana.

(Catalog of Federal Domestic Assistance Number 59008)

Dated: September 8, 2016.

Maria Contreras-Sweet,

Administrator.

[FR Doc. 2016–22409 Filed 9–15–16; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[License No. 09/09–0479]

Avante Mezzanine Partners SBIC II, L.P.; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that Avante Mezzanine Partners SBIC II, L.P., 11150 Santa Monica Boulevard, Suite 1470, Los Angeles, CA 90025, a Federal Licensee under the Small Business Investment Act of 1958, as amended ("the Act"), in connection with the financing of a small concern, has sought an exemption under Section 312 of the Act and Section 107.730, Financings which constitute Conflicts of Interest of the Small Business Administration ("SBA") Rules and Regulations (13 CFR 107.730). Avante Mezzanine Partners SBIC II, L.P. proposes to provide debt and equity financings to Learner's Edge LLC, 10523 165th Street West, Lakeville, MN 55044.

The financing is brought within the purview of § 107.730(a)(1) of the Regulations because Avante Mezzanine Partners SBIC, L.P and Avante Mezzanine Partners SBIC II, L.P. are Associates. Avante Mezzanine Partners SBIC, L.P owns more than 10 percent of Learner's Edge LLC and therefore this transaction is considered *Financing an Associate* requiring prior SBA approval.

Notice is hereby given that any interested person may submit written comments on this transaction within fifteen days of the date of this publication to the Associate Administrator, Office of Investment and Innovation, U.S. Small Business Administration, 409 Third Street SW., Washington, DC 20416.

Mark L. Walsh,

Associate Administrator for Office of Investment and Innovation.

[FR Doc. 2016–22414 Filed 9–15–16; 8:45 am]

BILLING CODE P

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2016–0044]

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov*

(SSA), Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov*

Or you may submit your comments online through *www.regulations.gov,* referencing Docket ID Number [SSA–2016–0044].

I. The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than November 15, 2016. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. *Request for Corrections of Earnings Record—20 CFR 404.820 and 20 CFR 422.125—0960–0029.* Individuals alleging inaccurate earnings records in SSA's files use paper Form SSA–7008, or a personal interview during which SSA employees key their answers into our electronic Earnings Modernization Item Correction system, to provide the information SSA needs to check earnings posted, and, as necessary, initiate development to resolve any inaccuracies. The respondents are individuals who request correction of earnings posted to their Social Security earnings record.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minute)	Estimated annual burden (hours)
Paper form	37,500	1	10	6,250
In-person or telephone interview	337,500	1	10	56,250
Total	375,000			62,500

2. *Employer Reports of Special Wage Payments—20 CFR 404.428–404.429–0960–0565.* SSA collects information on the SSA–131 to prevent earnings-related overpayments, and to avoid erroneous withholding of benefits. SSA field offices and program service centers also use Form SSA–131 for awards and post-entitlement events requiring special wage payment verification from employers. While we need this information to ensure the correct payment of benefits, we do not require employers to respond. The respondents are large and small businesses that make special wage payments to retirees

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minute)	Estimated annual burden (hours)
Paper Version: SSA–131 (without #6)	105,000	1	20	35,000
Paper Version: SSA–131 (#6 only)	1,050	1	2	35
Electronic Version: Business Services Online Special Wage Payments	26		5	2
Totals	106,076			35,037

II. SSA submitted the information collection below to OMB for clearance. Your comments regarding the information collection would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than October 17, 2016. Individuals can obtain copies of the OMB clearance package by writing to *OR.Reports.Clearance@ssa.gov.*

Certificate of Coverage Request—20 CFR 404.1913—0960–0554. The United States maintains agreements with 27 foreign countries to eliminate double Social Security coverage and taxation where, except for the provisions of the agreement, a worker would be subject to coverage and taxes in both countries. These agreements contain rules for determining the country under whose laws the worker's period of employment is covered, and to which country the worker will pay taxes. The agreements further dictate that, upon the request of the worker or employer, the country under whose system the period of work is covered will issue a certificate of coverage. The certificate serves as proof of exemption from coverage and taxation under the system of the other country. The information we collect assists us in determining a worker's coverage and in issuing a U.S. certificate of coverage as appropriate. Per our agreements, we ask a set number of questions to the workers and employers prior to issuing a certificate of coverage; however, our agreements with Denmark, Netherlands, Norway, and Sweden require us to ask more questions in those countries. Respondents are workers and employers wishing to establish exemption from foreign Social Security taxes.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minute)	Estimated annual burden (hours)
Requests via Letter—Individuals (minus Denmark, Netherlands, Norway, Poland & Sweden)	6,272	1	40	4,181
Requests via Internet—Individuals (minus Denmark, Netherlands, Norway, Poland & Sweden)	9,407	1	40	6,271
Requests via Letter—Individuals in Denmark, Netherlands, Norway, & Sweden	280	1	44	205
Requests via Letter—Individuals in Poland	16	1	41	11
Requests via Internet—Individuals in Denmark, Netherlands, Norway, & Sweden	421	1	44	309
Requests via Internet—Individuals in Poland	23	1	41	16
Requests via Letter—Employers (minus Denmark, Netherlands, Norway, Poland & Sweden)	25,087	1	40	16,725
Requests via Internet—Employers (minus Denmark, Netherlands, Norway, Poland, & Sweden)	37,632	1	40	25,088
Requests via Letter—Employers in Denmark, Netherlands, Norway, & Sweden	1,121	1	44	822
Requests via Letter—Employers in Poland	62	1	41	42
Requests via Internet—Employers in Denmark, Netherlands, Norway, & Sweden	1,680	1	44	1,232
Requests via Internet—Employers in Poland	93	1	41	64
Totals	82,094			54,966

Dated: September 13, 2016.

Naomi R. Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2016–22277 Filed 9–15–16; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice: 9716]

Culturally Significant Objects Imported for Exhibition Determinations: "The Art of Alchemy" Exhibition

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition "The Art of Alchemy," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Getty Research Institute at the Getty Center, Los Angeles, California, from on or about October 11, 2016, until on or about February 12, 2017, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: September 8, 2016.

Mark Taplin,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2016–22371 Filed 9–15–16; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice 9701]

Notice of Information Collection Under OMB Emergency Review: Affidavit of Relationship (AOR) for Minors Who Are Nationals of El Salvador, Guatemala, or Honduras

ACTION: Notice of request for emergency OMB approval and public comment.

SUMMARY: The Department of State has submitted the information collection request described below to the Office of Management and Budget (OMB) for review and approval in accordance with the emergency review procedures of the Paperwork Reduction Act of 1995 (5 CFR 1320.13). The purpose of this notice is to allow for public comment from all interested individuals and organizations. Emergency review and approval of this collection has been requested from OMB by September 30, 2016. If granted, the emergency approval will only be valid for a maximum of 180 days. The Department plans to follow this emergency request with a submission for a three year approval through OMB's normal PRA clearance process (5 CFR 1320.10).

ADDRESSES: Direct any comments on this emergency request to both the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB) and to the Bureau of Population, Refugees and Migration (PRM), Office of Refugee Admissions.

All public comments must be received by September 26, 2016.

You may submit comments to OMB by the following methods:

- *Email: oira_submission@omb.eop.gov.* You should include the DS form number, information collection title, and OMB control number in the subject line of your message.
- *Fax:* 202–395–5806. Attention: Desk Officer for Department of State.

You may submit comments to PRM/Office of Admissions by the following methods:

- *Web:* Persons with access to the Internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering "Docket Number: DOS–2016–0060" in the Search field. Then click the "Comment Now" button and complete the comment form.
- *Email: GrecoMC@state.gov.* You must include "Emergency Submission Comment on Affidavit of Relationship (AOR) for Minors who are Nationals of El Salvador, Guatemala, or Honduras" in the subject line of your message.
- *Regular Mail:* Send written comments to: Monica Greco, PRM/Office of Admissions, 2025 E Street NW., Washington, DC 20522.

You should include the DS form number, information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents to Monica Greco, PRM/Office of Admissions, 2025 E Street NW., Washington, DC 20522, who may be reached on 202–453–9251 or at *GrecoMC@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Affidavit of Relationship (AOR) for Minors Who Are Nationals of El Salvador, Guatemala, and Honduras.
- *OMB Control Number:* 1405–0217.
- *Type of Request:* Emergency Review.
- *Originating Office:* PRM/A.
- *Form Number:* DS–7699.
- *Respondents:* Lawfully present parents in the U.S. with children in El Salvador, Guatemala, and Honduras.
- *Estimated Number of Respondents:* 5,000.
- *Estimated Number of Responses:* 5,000.
- *Average Time Per Response:* 120 minutes per response.
- *Total Estimated Burden Time:* 10,000 hours.
- *Frequency:* Once per respondent.
- *Obligation to respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden of this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review

Abstract of proposed collection: The Department of State Bureau of Population, Refugees, and Migration (PRM) is responsible for coordinating and managing the U.S. Refugee Admissions Program (USRAP). PRM coordinates within the Department of State, as well as with the Department of Homeland Security's U.S. Citizenship and Immigration Services (DHS/USCIS), in carrying out this responsibility. A critical part of the State Department's responsibility is determining which individuals, from among millions of refugees worldwide, will have access to U.S. resettlement consideration. PRM and DHS/USCIS are expanding an in-country program to provide a means for certain persons who are lawfully present in the United States to claim a relationship with child(ren) in Honduras, El Salvador, and Guatemala and to assist the U.S. Department of State in determining whether those child(ren) and certain derivative beneficiaries are qualified to apply for access to the USRAP for family reunification purposes. This form also assists DHS/USCIS to verify parent-child relationships during refugee case adjudication. The main purpose of the DS–7699 is for the U.S.-based parent to provide biographical information about his/her child(ren) in the qualifying countries who may subsequently seek access to the USRAP for verification by the U.S. government.

Methodology: This information collection currently involves use of electronic techniques. Parents (respondents) in the United States will work closely with a resettlement agency during the completion of the AOR to ensure that the information is accurate. Parents may visit any resettlement agency located in a U.S. community to complete an AOR. Sometimes respondents do not have strong English-language skills and benefit from having a face-to-face meeting with resettlement agency staff. The DS–7699 form will be completed electronically. Completed AORs will be printed out for ink signature by the respondents. The electronic copy will then be submitted electronically to the Refugee Processing Center (RPC) and downloaded into the Worldwide Refugee Admissions Processing System (WRAPS). The signed paper copy will remain with PRM's Reception and Placement Agency partners.

Dated: September 6, 2016.

Mark Storella,

Deputy Assistant Secretary, Bureau of Population, Refugees, and Migration, Department of State.

[FR Doc. 2016–22358 Filed 9–15–16; 8:45 am]

BILLING CODE 4710–33–P

DEPARTMENT OF STATE

[Public Notice 9720]

60-Day Notice of Proposed Information Collection: Request for Advisory Opinion

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public until November 15, 2016.

ADDRESSES: You may submit comments by any of the following methods:

- *Internet:* Persons with access to the Internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering "Docket Number: DOS–2016–0062" in the Search field. Then click the "Comment Now" button and complete the comment form.
- *Email: DDTCPublicComments@state.gov,* ATTN: Advisory Opinion Form.
- *Regular Mail:* Send written comments to: Directorate of Defense Trade Controls, Department of State; 2401 E St. NW., Suite H1205, Washington, DC 20522. You must include the DS form number, information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Steve Derscheid, Directorate of Defense Trade Controls, Department of State, who may be reached at *DerscheidSA@state.gov* (please include subject line "ATTN: Advisory Opinion Form").

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Request for Advisory Opinion.
- *OMB Control Number:* 1405–0174.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* T/PM/DDTC.
- *Form Number:* DS–7786.
- *Respondents:* Individuals and companies engaged in the business of exporting or temporarily importing defense articles or defense services.
- *Estimated Number of Respondents:* 250.
- *Estimated Number of Responses:* 250.
- *Average Time Per Response:* 2 hours.
- *Total Estimated Burden Time:* 500 hours.
- *Frequency:* On occasion.
- *Obligation to Respond:* Voluntary.

We are soliciting public comments to permit the Department to:

- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of proposed collection: The Directorate of Defense Trade Controls (DDTC), located in the Political-Military Affairs Bureau of the Department of State, has the principal mission of licensing the export and temporary import of defense articles or defense services as enumerated in the United States Munitions List (USML), and to ensure that the sale, transfer, or brokering of such items are in the interest of United States national security and foreign policy.

Sections 126.9 and 129.9 of the International Traffic in Arms Regulations (ITAR, 22 CFR 120–130) may be used by entities and individuals involved in the brokering, manufacture, export, and temporary import of defense articles and defense services to request an advisory opinion as to whether DDTC would be likely to grant a license or other approval for the export of a particular defense article or defense service to a particular country; for general or regulatory guidance; or whether certain activity constitutes brokering under the meaning of the ITAR. Except for determinations made with reference to ITAR § 129.9(b), advisory opinions are not binding on the Department of State and may not be used in future matters before the Department.

DDTC has recently acquired an electronic case management system to update its business processes and how it receives and handles information from industry. This system, once deployed, will allow users to electronically submit requests for advisory opinions to DDTC; users will be able to retrieve responses using the same system. DDTC staff members have defined the data fields which are most relevant and necessary for requests for advisory opinions and developed the means to accept this information from the industry in a secure system. The revision of this information collection is meant to conform the current OMB-approved data collection to DDTC's new case management system. DDTC is therefore requesting industry comments on the new advisory opinion form, which will be mirrored in the case management system once deployed. A copy of the draft form may be requested from DDTC using the contact information in the **FOR FURTHER INFORMATION CONTACT** section above, and a copy of the draft form will also be placed for viewing on the DDTC Web site at *pmddtc.state.gov.*

Methodology: This information will be collected by electronic submission to the Directorate of Defense Trade Controls.

Dated: August 22, 2016.

Lisa Aguirre,

Managing Director, Directorate of Defense Trade Controls, Department of State.

[FR Doc. 2016–22354 Filed 9–15–16; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF STATE

[Public Notice: 9629]

Registration for the Diversity Immigrant (DV–2018) Visa Program

AGENCY: Bureau of Consular Affairs, Department of State.

ACTION: Notice.

SUMMARY: This public notice provides information on how to apply for the DV–2018 Program.

SUPPLEMENTARY INFORMATION:

Program Overview

The Department of State administers the Congressionally-mandated Diversity Immigrant Visa Program annually. Section 203(c) of the Immigration and Nationality Act (INA) provides for a class of immigrants known as "diversity immigrants," from countries with historically low rates of immigration to the United States. For fiscal year 2018, 50,000 diversity visas (DVs) will be available. There is no cost to register for the DV Program.

Applicants who are selected in the lottery ("selectees") must meet simple, but strict, eligibility requirements to qualify for a diversity visa. The Department of State determines selectees through a randomized computer drawing. Diversity visa numbers are distributed among six geographic regions and no single country may receive more than seven percent of the available DVs in any one year.

For DV–2018, natives of the following countries are not eligible to apply, because more than 50,000 natives of these countries immigrated to the United States in the previous five years:

Bangladesh, Brazil, Canada, China (mainland-born), Colombia, Dominican Republic, El Salvador, Haiti, India, Jamaica, Mexico, Nigeria, Pakistan, Peru, Philippines, South Korea, United Kingdom (except Northern Ireland) and its dependent territories, and Vietnam.

Persons born in Hong Kong SAR, Macau SAR, and Taiwan are eligible.

Changes in eligibility this year: Ecuador is eligible for DV 2018.

Eligibility

Requirement #1: Individuals born in countries whose natives qualify may be eligible to enter.

If you were not born in an eligible country, there are two other ways you might be able to qualify.

- Was your spouse born in a country whose natives are eligible? If yes, you can claim your spouse's country of birth—provided that both you and your spouse are named on the selected entry, are found eligible for and issued diversity visas, and enter the United States simultaneously.
- Were you born in a country whose natives are ineligible, but in which neither of your parents were born or legally resident at the time of your birth? If yes, you may claim the country of birth of one of your parents if it is a country whose natives are eligible for the DV–2018 program. For more details on what this means, see the Frequently Asked Questions.

Requirement #2: Each applicant must meet the education/work experience requirement of the DV program by having either:

- At least a high school education or its equivalent, defined as successful completion of a 12-year course of formal elementary and secondary education; OR
- two years of work experience within the past five years in an occupation that requies at least two years of training or experience to perform. The Department of State will use the U.S. Department of Labor's O*Net Online database to determine qualifying work experience. For more information about qualifying work experience for the principal DV applicant, see the Frequently Asked Questions.

Do not submit an entry to the DV program unless you meet both of these requirements.

Entry Period

Applicants must submit entries for the DV–2018 DV program electronically at *dvlottery.state.gov* between noon, Eastern Daylight Time (EDT) (GMT–4), Tuesday, October 4, 2016, and noon, Eastern Standard Time (EST) (GMT–5), Monday, November 7, 2016. Do not wait until the last week of the registration period to enter, as heavy demand may result in Web site delays. No late entries or paper entries will be accepted. The law allows only one entry by or for each person during each registration period. The Department of State uses sophisticated technology to detect multiple entries. Individuals with more than one entry will be disqualified.

Completing Your Electronic Entry for the DV–2018 Program

Submit your Electronic Diversity Visa Entry Form (E–DV Entry Form or DS-5501), online at *dvlottery.state.gov*. We will not accept incomplete entries. There is no cost to register for the DV Program.

We strongly encourage you to complete the entry form yourself, without a "visa consultant," "visa agent," or other facilitator who offers to help. If someone else helps you, you should be present when your entry is prepared so that you can provide the correct answers to the questions and retain the confirmation page and your unique confirmation number.

After you submit a complete entry, you will see a confirmation screen that contains your name and a unique confirmation number. Print this confirmation screen for your records. It is extremely important that you retain your confirmation page and unique confirmation number. Without this information, you will not be able to access the online system that will inform you of the status of your entry.

You also should retain access to the email account listed in the E–DV. See the Frequently Asked Questions for more information about Diversity Visa scams. Starting May 2, 2017, you will be able to check the status of your entry by returning to *dvlottery.state.gov,* clicking on *Entrant Status Check,* and entering your unique confirmation number and personal information. *Entrant Status Check* will be the sole means of informing you of your selection for DV–2018, providing instructions on how to proceed with your application, and notifying you of your appointment for your immigrant visa interview. Please review the Frequently Asked Questions for more information about the selection process.

You must provide the following information to complete your E–DV entry:

1. Name—last/family name, first name, middle name—exactly as on your passport.

2. Gender—male or female.

3. Birth date—day, month, year.

4. City where you were born.

5. Country where you were born—Use the name of the country currently used for the place where you were born.

6. Country of eligibility for the DV Program—Your country of eligibility will normally be the same as your country of birth. Your country of eligibility is not related to where you live.

If you were born in a country that is not eligible, please review the Frequently Asked Questions to see if there is another way you may be eligible.

7. Entrant photograph(s)—Recent photographs (taken within 6 months) of yourself, your spouse, and all your children listed on your entry. See Submitting a Digital Photograph for compositional and technical specifications. You do not need to include a photograph for a spouse or child who is already a U.S. citizen or a Lawful Permanent Resident, but you will not be penalized if you do. We cannot accept group photographs; you must submit a photograph for each individual. Your entry may be disqualified or your visa refused if the photographs are more than six months old, have been manipulated in any way, or do not meet the specifications explained below. Submitting the same photograph that you submitted with last year's entry (DV–2017) will result in disqualification. See Submitting a Digital Photograph for more information.

8. Mailing Address—In Care Of
Address Line 1
Address Line 2
City/Town
District/Country/Province/State
Postal Code/Zip Code
Country

9. Country where you live today.

10. Phone number (optional).

11. Email address—An email address to which you have direct access, and will continue to have direct access after we notify selectees in May of next year. If your entry is selected and you respond to the notification of your selection through the *Entrant Status Check,* you will receive follow-up email communication from the Department of State notifying you that details of your immigrant visa interview are available on *Entrant Status Check.* The Department of State will never send you an email telling you that you have been selected for the DV program. See the Frequently Asked Questions for more information about the selection process.

12. Highest level of education you have achieved, as of today: (1) Primary school only, (2) Some high school, no diploma, (3) High school diploma, (4) Vocational school, (5) Some university courses, (6) University degree, (7) Some graduate-level courses, (8) Master's degree, (9) Some doctoral-level courses, and (10) Doctorate. See the Frequently Asked Questions for more information about educational requirements.

13. Current marital status—(1) Unmarried, (2) married and my spouse is NOT a U.S. citizen or U.S. LPR, (3) married and my spouse IS a U.S. citizen or U.S. LPR, (4) divorced, (5) widowed, or (6) legally separated. Enter the name, date of birth, gender, city/town of birth, country of birth of your spouse, and a photograph of your spouse meeting the same technical specifications as your photo.

Failure to list your eligible spouse will result in disqualification of the principal applicant and refusal of all visas in the case at the time of the visa interview. You must list your spouse even if you currently are separated from him/her, unless you are legally separated (*i.e.,* there is a written agreement recognized by a court or a court order). A spouse who is already a U.S. citizen or a Lawful Permanent Resident will not require or be issued a DV visa. Therefore, if you select "married and my spouse IS a U.S. citizen or U.S. LPR" on your entry, you will not be prompted to include further information on your spouse. See the Frequently Asked Questions for more information about family members.

14. Number of children—List the Name, date of birth, gender, city/town of birth, and country of birth for all living unmarried children under 21 years of age, regardless. Submit individual photographs of each of your children using the same technical specifications as your own photograph.

Be sure to include:

- All living natural children;
- all living children legally adopted by you; and,
- all living step-children who are unmarried and under the age of 21 on the date of your electronic entry, even if you are no longer legally married to the child's parent, and even if the child does not currently reside with you and/or will not immigrate with you.

Married children and children over the age of 21 are not eligible for the DV. However, the Child Status Protection Act protects children from "aging out" in certain circumstances. If you submit your DV entry before your unmarried child turns 21, and the child turns 21 before visa issuance, it is possible that he or she may be treated as though he or she were under 21 for visa-processing purposes.

A child who is already a U.S. citizen or a Lawful Permanent Resident will not require or be issued a diversity visa, and you will not be penalized for either including or omitting such family members from your entry.

Failure to list all children who are eligible will result in disqualification of the principal applicant and refusal of all visas in the case at the time of the visa interview. See the Frequently Asked Questions for more information about family members.

See the Frequently Asked Questions for more information about completing your Electronic Entry for the DV–2018 Program.

Selection of Applicants

Based on the allocations of available visas in each region and country, the Department of State will randomly select individuals by computer from among qualified entries. All DV–2018 entrants must go to the *Entrant Status Check* using the unique confirmation number saved from their DV–2018 online entry registration to find out whether their entry has been selected in the DV program. *Entrant Status Check* will be available on the E–DV Web site at *dvlottery.state.gov* starting May 2, 2017, through at least September 30, 2018.

If your entry is selected, you will be directed to a confirmation page that will provide further instructions, including information on fees connected with immigration to the United States. *Entrant Status Check* will be the ONLY means by which the Department of State notifies selectees of their selection for

DV–2018. The Department of State will not mail out notification letters or notify selectees by email. U.S. embassies and consulates will not provide a list of selectees. Individuals who have not been selected also will be notified ONLY through *Entrant Status Check*. You are strongly encouraged to access *Entrant Status Check* yourself and not to rely on someone else to check and inform you.

In order to immigrate, DV selectees must be admissible to the United States. The DS–260, Online Immigrant Visa and Alien Registration Application, electronically, and the consular officer, in person will ask you questions about your eligibility to immigrate, and these questions include criminal and security related grounds.

All eligible selectees, including family members, must be issued by September 30, 2018. Under no circumstances can the Department of State issue DVs or approve adjustments after this date, nor can family members obtain DVs to follow-to-join the principal applicant in the United States after this date. See the Frequently Asked Questions for more information about the selection process.

Submitting a Digital Photograph (Image)

You can take a new digital photograph or scan a recent photographic print, taken within the last 6 months, with a digital scanner, as long as it meets the compositional and technical specifications listed below. Test your photos through the photo validation link on the E–DV Web site, which provides additional technical advice on photo composition and examples of acceptable and unacceptable photos. Do not submit an old photograph. Submitting the same photograph that was submitted with last year's entry will result in disqualification.

Photographs must be in 24-bit color depth. If you are using a scanner, the settings must be for True Color or 24-bit color mode. See the additional scanning requirements below.

Compositional Specifications

- *Head Position:* You must directly face the camera. The subject's head should not be tilted up, down, or to the side. The head height or facial region size (measured from the top of the head, including the hair, to the bottom of the chin) must be between 50 percent and 69 percent of the image's total height. The eye height (measured from the bottom of the image to the level of the eyes) should be between 56 percent and 69 percent of the image's height.
- *Light-colored Background*: The subject should be in front of a neutral, light-colored background.
- *Focus:* The photograph must be in focus.
- *No Eyewear:* The subject must not wear glasses or other items that detract from the face.
- *No Head Coverings or Hats:* Head coverings or hats worn for religious beliefs are acceptable, but the head covering may not obscure any portion of the face. Tribal or other headgear not religious in nature may not be worn. Photographs of military, airline, or other personnel wearing hats will not be accepted.

Technical Specifications

- Taking a New Digital Image. If you submit a new digital image, it must meet the following specifications:

Image File Format: The image must be in the Joint Photographic Experts Group (JPEG) format.

Image File Size: The maximum image file size is 240 kilobytes (240KB).

Image Resolution and Dimensions: Minimum acceptable dimensions are 600 pixels (width) x; 600 pixels (height) up to 1200 pixels x 1200 pixels. Image pixel dimensions must be in a square aspect ratio (meaning the height must be equal to the width).

Image Color Depth: Image must be in color (24 bits per pixel). 24-bit black and white or 8-bit images will not be accepted.

- Scanning a Submitted Photograph. Before you scan a photographic print, make sure it meets the color and compositional specifications listed above. Scan the print using the following scanner specifications:

Scanner Resolution: Scanned at a resolution of at least 300 dots per inch (dpi).

Image File Format: The image must be in the Joint Photographic Experts Group (JPEG) format.

Image File Size: The maximum image file size is 240 kilobytes (240 KB).

Image Color Depth: 24-bit color. [Note that black and white, monochrome, or grayscale images will not be accepted.]

Frequently Asked Questions (FAQ's)

Eligibility

1. What do the terms "native" and "chargeability" mean?

"Native" ordinarily means someone born in a particular country, regardless of the individual's current country of residence or nationality. "Native" can also mean someone who is entitled to be "charged" to a country other than the one in which he/she was born under the provisions of Section 202(b) of the Immigration and Nationality Act.

Because there is a numerical limitation on immigrants who enter from a country or geographic region, each individual is "charged" to a country. Your "chargeability" refers to the country towards which limitation you count. Your country of eligibility will normally be the same as your country of birth. However, you may choose your country of eligibility as the country of birth of your spouse, or the country of birth of either of your parents if you were born in a country in which neither parent was born and in which the parents were not resident at the time of your birth. These are the only three ways to select your country of chargeability.

If you claim alternate chargeability through either of the above, you must provide an explanation on the E–DV Entry Form, in question #6. Listing an incorrect country of eligibility or chargeability (*i.e.,* one to which you cannot establish a valid claim) will disqualify your entry.

2. Can I still apply if I was not born in a qualifying country?

There are two circumstances in which you still might be eligible to apply. First, if your derivative spouse was born in an eligible country, you may claim chargeability to that country. As your eligibility is based on your spouse, you will only be issued a DV–1 immigrant visa if your spouse is also eligible for and issued a DV–2 visa. Both of you must enter the United States together using your DVs. Similarly, your minor dependent child can be "charged" to a parent's country of birth.

Second, you can be "charged" to the country of birth of either of your parents as long as neither of your parents was born in or a resident of your country of birth at the time of your birth. People are not generally considered residents of a country in which they were not born or legally naturalized, if they were only visiting, studying in the country temporarily, or stationed temporarily for business or professional reasons on behalf of a company or government from a different country other than the one in which you were born.

If you claim alternate chargeability through either of the above, you must provide an explanation on the E–DV Entry Form, in question #6. Listing an incorrect country of eligibility or chargeability (*i.e.,* one to which you cannot establish a valid claim) will disqualify your entry.

3. Why do natives of certain countries not qualify for the DV program?

DVs are intended to provide an immigration opportunity for persons who are not from "high admission" countries. The law defines "high admission countries'' as those from which a total of 50,000 persons in the Family-Sponsored and Employment-Based visa categories immigrated to the United States during the previous five years. Each year, U.S. Citizenship and Immigration Services (USCIS) counts the family and employment immigrant admission and adjustment of status numbers for the previous five years to identify the countries that are considered ''high admission'' and whose natives will therefore be ineligible for the annual diversity visa program. Because USCIS makes this calculation annually, the list of countries whose natives are eligible or not eligible may change from one year to the next.

4. How many DV–2018 visas will go to natives of each region and eligible country?

United States Citizenship and Immigration Services (USCIS) determines the regional DV limits for each year according to a formula specified in Section 203(c) of the Immigration and Nationality Act (INA). The number of visas the Department of State eventually will issue to natives of each country will depend on the regional limits established, how many entrants come from each country, and how many of the selected entrants are found eligible for the visa. No more than seven percent of the total visas available can go to natives of any one country.

5. What are the requirements for education or work experience?

U.S. immigration law and regulations require that every DV entrant must have at least a high school education or its equivalent or have two years of work experience within the past five years in an occupation that requires at least two years of training or experience. A ''high school education or equivalent'' is defined as successful completion of a 12-year course of elementary and secondary education in the United States OR the successful completion in another country of a formal course of elementary and secondary education comparable to a high school education in the United States. Only formal courses of study meet this requirement; correspondence programs or equivalency certificates (such as the General Equivalency Diploma G.E.D.) are not acceptable. You must present documentary proof of education or work experience to the consular officer at the time of the visa interview.

If you do not meet the requirements for education or work experience, your entry will be disqualified at the time of your visa interview, and no visas will be issued to you or any of your family members.

6. What occupations qualify for the DV program?

The U.S. Department of Labor's (DOL) O*Net OnLine database will be used to determine qualifying work experience. The O*Net Online Database groups job experience into five ''job zones.'' While the DOL Web site lists many occupations, not all occupations qualify for the DV Program. To qualify for a DV on the basis of your work experience, you must have, within the past five years, two years of experience in an occupation that is classified in a Specific Vocational Preparation (SVP) range of 7.0 or higher.

If you do not meet the requirements for education or work experience, your entry will be disqualified at the time of your visa interview, and no visas will be issued to you or any of your family members.

7. How can I find the qualifying DV occupations in the Department of Labor's O*Net online database?

When you are in O*Net OnLine, follow these steps to find out if your occupation qualifies:

1. Under ''Find Occupations'' select ''Job Family'' from the pull down;
2. Browse by ''Job Family'', make your selection, and click ''GO'';
3. Click on the link for your specific occupation.
4. Select the tab ''Job Zone'' to find the designated Job Zone number and Specific Vocational Preparation (SVP) rating range.

As an example, select Aerospace Engineers. At the bottom of the Summary Report for Aerospace Engineers, under the Job Zone section, you will find the designated Job Zone 4, SVP Range, 7.0 to < 8.0. Using this example, Aerospace Engineering is a qualifying occupation.

For additional information, see the Diversity Visa—List of Occupations Web page *(travel.state.gov/visa/immigrants/types/types_1319.html).*

8. Is there a minimum age to apply for the DV program?

There is no minimum age to apply, but the requirement of a high school education or work experience for each principal applicant at the time of application will effectively disqualify most persons who are under age 18.

Completing Your Electronic Entry for the DV Program

9. When can I submit my entry?

The DV–2018 entry period will run from 12:00 p.m. (noon), Eastern Daylight Time (EST) (GMT–4), Tuesday, October 4, 2016, until 12:00 p.m. (noon), Eastern Standard Time (EDT) (GMT–5), Monday, November 7, 2016. Each year, millions of people submit entries. Holding the entry period on these dates ensures selectees receive notification in a timely manner and gives both the visa applicants and our embassies and consulates time to prepare and complete cases for visa issuance.

We strongly encourage you to enter early during the registration period. Excessive demand at the end of the registration period may slow the system down. We cannot accept entries after noon EST Monday, November 7, 2016.

10. I am in the United States. Can I enter the DV program?

Yes, an entrant may be in the United States or in another country, and the entrant may submit an entry from anywhere.

11. Can I only enter once during the registration period?

Yes, the law allows only one entry by or for each person during each registration period. The Department of State uses sophisticated technology to detect multiple entries. *Individuals with more than one entry will be disqualified.*

12. May my spouse and I each submit a separate entry?

Yes, a husband and a wife may each submit one entry if each meets the eligibility requirements. If either spouse is selected, the other is entitled to apply as a derivative dependent.

13. What family members must I include in my DV entry?

Spouse: If you are legally married, you must list your spouse (husband or wife) regardless . You must list your spouse even if you are currently separated from him/her, unless you are legally separated (*i.e.,* there is a written agreement recognized by a court or a court order). If you are legally separated, you do not have to list your spouse, though you will not be penalized if you do so. If you are divorced or your spouse is deceased, you do not have to list your former spouse.

The only exception to this requirement is if your spouse is already a U.S. citizen or U.S. Lawful Permanent Resident. A spouse who is already a U.S. citizen or a Lawful Permanent Resident will not require or be issued a DV. Therefore, if you select ''married and my spouse IS a U.S. citizen or U.S. LPR'' on your entry, you will not be able to include further information on your spouse.

Children: You must list ALL your living children who are unmarried and under 21 years of age at the time of your initial E–DV entry, whether they are your natural children, your stepchildren (even if you are now divorced from that child's parent), your spouse's children, or children you have formally adopted in accordance with the applicable laws. List all children under 21 years of age at the time of your electronic entry, even if they no longer reside with you or you do not intend for them to immigrate under the DV program. You are not required to list children who are already U.S. citizens or Lawful Permanent Residents, though you will not be penalized if you do include them.

Parents and siblings of the entrant are ineligible to receive DV visas as dependents, and you should not include them in your entry.

If you list family members on your entry, they are not required to apply for a visa or to immigrate or travel with you. However, if you fail to include an eligible dependent on your original entry, your case will be disqualified at the time of your visa interview and no visas will be issued to you or any of your family members. This only applies to those who were family members at the time the original application was submitted, not those acquired at a later date. Your spouse, if eligible to enter, may still submit a separate entry even though he or she is listed on your entry, as long as both entries include details on all dependents in your family (see FAQ #12 above).

14. Must I submit my own entry, or can someone else do it for me?

We encourage you to prepare and submit your own entry, but you may have someone submit the entry for you. Regardless of whether you submit your own entry, or an attorney, friend, relative, or someone else submits it on your behalf, only one entry may be submitted in your name. You, as the entrant, are responsible for ensuring that information in the entry is correct and complete; entries that are not correct or complete may be disqualified. Entrants should keep their own confirmation number so that they are able to independently check the status of their entry using Entrant Status Check at *dvlottery.state.gov.* Entrants should keep retain access to the email account used in the E–DV submission.

15. I'm already registered for an immigrant visa in another category. can I still apply for the DV program?

Yes. Your DV registration will not make you ineligible for another immigrant visa classification.

16. When will E–DV be available online?

You can enter online during the registration period beginning at 12:00 p.m. (noon) Eastern Daylight Time (EDT) (GMT–4) on Tuesday, October 4, 2016, and ending at 12:00 p.m. (noon) Eastern Standard Time (EST) (GMT–5) on Monday, November 7, 2016.

17. Can I download and save the E–DV entry form into a word processing program and finish it later?

No, you will not be able to save the form into another program for completion and submission later. The E–DV Entry Form is a Web form only. You must fill in the information and submit it while online.

18. Can I save the form online and finish it later?

No. The E–DV Entry Form is designed to be completed and submitted at one time. You will have sixty (60) minutes starting from when you download the form to complete and submit your entry through the E–DV Web site. If you exceed the sixty minute limit and have not submitted your complete entry electronically, the system discards any information already entered. The system deletes any partial entries so that they are not accidentally identified as duplicates of a later, complete entry. Read the DV instructions completely before you start to complete the form online, so that you know exactly what information you will need.

19. I don't have a scanner. Can I send photographs to someone in the United States to scan them, save them, and mail them back to me so I can use them in my entry?

Yes, as long as the photograph meets the requirements in the instructions and is electronically submitted with, and at the same time as, the E–DV online entry. You must already have the scanned photograph file when you submit the entry online; it cannot be submitted separately from the online application. The entire entry (photograph and application together) can be submitted electronically from the United States or from overseas.

20. According to the procedures, the system will reject my E–DV entry form if my photos don't meet the specifications. Can I resubmit my entry?

Yes, as long as you complete your submission by 12:00 p.m. (noon) Eastern Standard Time (EST) (GMT–5) on Monday, November 7, 2016. If your photo(s) did not meet the specifications, the E–DV Web site will not accept your entry, so you will not receive a confirmation notice. However, given the unpredictable nature of the Internet, you may not receive the rejection notice immediately. If you can correct the photo(s) and re-send the Form Part One or Two within sixty (60) minutes, you may be able to successfully submit the entry. Otherwise, you will have to restart the entire entry process. You can try to submit an application as many times as is necessary until a complete application is submitted and you receive the confirmation notice. Once you receive a confirmation notice, your entry is complete and you should NOT submit any additional entries.

21. How soon after I submit my entry will I receive the electronic confirmation notice?

You should receive the confirmation notice immediately, including a confirmation number that you must record and keep. However, the unpredictable nature of the Internet can result in delays. You can hit the "Submit" button as many times as is necessary until a complete application is submitted and you receive the confirmation notice. However, once you receive a confirmation notice, do not resubmit your information.

22. I hit the "Submit" button, but did not receive a confirmation number. If I submit another entry, will I be disqualified?

If you did not receive a confirmation number, your entry was not recorded. You must submit another entry. It will not be counted as a duplicate. Once you receive a confirmation number, do not resubmit your information.

Selection

23. How do I know if I am selected?

You must use your confirmation number to access the Entrant Status Check available on the E–DV Web site at *dvlottery.state.gov* starting May 2, 2017 through September 30, 2018. Entrant Status Check is the sole means by which the Department of State will notify you if you are selected, provided further instructions on your visa application, and notify you of your immigrant visa interview appointment date and time. The only authorized Department of State Web site for official online entry in the Diversity Visa Program and Entrant Status Check is *dvlottery.state.gov.*

The Department of State will NOT contact you to tell you that you have been selected (see FAQ #24).

24. How will I know if I am not selected? Will I be notified?

You may check the status of your DV–2018 entry through the Entrant Status Check on the E–DV Web site at *dvlottery.state.gov* starting May 2, 2017, until September 30, 2018. Keep your confirmation number until at least September 30, 2018. (Status information for the previous year's DV program, DV–2017, is available online from May 5, 2016, through September 30, 2017.) If your entry is not selected, you will not receive any additional instructions.

25. What if I lose my confirmation number?

You must have your confirmation number to access Entrant Status Check. A tool is now available in Entrant Status Check (ESC) on the eDV Web site that will allow you to retrieve your confirmation number via the email address with which you registered by entering certain personal information to confirm your identity.

U.S. Embassies and Consulates and the Kentucky Consular Center are unable to check your selection status for you or provide your confirmation number to you directly (other than through the ESC retrieval tool). The Department of State is NOT able to provide a list of those selected to continue the visa process.

26. Will I receive information from the Department of State by email or by postal mail?

The Department of State will not send you a notification letter. The U.S. government has never sent emails to notify individuals that they have been selected, and there are no plans to use email for this purpose for the DV–2018 program. If you are a selectee, you will only receive email communications regarding your visa appointment *after* you have responded to the notification instructions on Entrant Status Check. These emails will not contain information on the actual appointment date and time; they will simply tell you that appointment details are available and you must then access Entrant Status Check for details. The Department of State may send emails reminding DV lottery applicants to check the ESC for their status. However, such emails will never indicate whether the lottery applicant was or was not selected.

Only Internet sites that end with the ".gov" domain suffix are official U.S. government Web sites. Many other Web sites (*e.g.,* with the suffixes ".com," ".org," or ".net") provide immigration and visa-related information and services. The Department of State does not endorse, recommend, or sponsor any information or material on these other Web sites.

You may receive emails from websites that try to trick you into sending money or providing your personal information. You may be asked to pay for forms and information about immigration procedures, all which are available free on the Department of State Web site or through U.S. Embassy or Consulate Web sites. Additionally, organizations or Web sites may try to steal your money by charging fees for DV-related services. If you send money to one of these scams, you will likely never see it again. Also, do not send personal information to these Web sites, as it may be used for identity fraud/theft.

These deceptive emails may come from people pretending to be affiliated with the Kentucky Consular Center or the Department of State. Remember the U.S. government has never sent emails to notify individuals that they have been selected, and will not use email to notify selectees for the DV–2018 program. The Department of State will never ask you to send money by mail or by services such as Western Union.

27. How many individuals will be selected for DV–2018?

For DV–2018, 50,000 DV visas are available. Because it is likely that some of the first 50,000 persons who are selected will not qualify for visas or not pursue their cases to visa issuance, more than 50,000 entries will be selected to ensure that all of the available DV visas are issued. However, this also means that there will not be a sufficient number of visas for all those who are initially selected. To maximize use of all available visas, the Department of State may update Entrant Status Check to include additional selectees at any time before the program ends on September 30, 2018.

You can check the E–DV Web site's Entrant Status Check to see if you have been selected for further processing and your place on the list. Interviews for the DV–2018 program will begin in October 2017 for selectees who have submitted all pre-interview paperwork and other information as requested in the notification instructions. Selectees who provide all required information will be informed of their visa interview appointment through the E–DV Web site's Entrant Status Check four to six weeks before the scheduled interviews with U.S. consular officers at overseas posts.

Each month, visas will be issued to those applicants who are eligible for issuance during that month, visa-number availability permitting. Once all of the 50,000 DV visas have been issued, the program will end. Visa numbers could be finished before September 2018. Selected applicants who wish to apply for visas must be prepared to act promptly on their cases. Being randomly chosen as a selectee does not guarantee that you will receive a visa. Selection merely means that you are eligible to apply for a Diversity Visa, and if your rank number becomes eligible for final processing, you potentially may be issued a Diversity Visa. Only 50,000 visas will be issued to such applicants.

28. How will successful entrants be selected?

Official notifications of selection will be made through Entrant Status Check, available starting May 2, 2017, through at least September 30, 2018, on the E–DV Web site *dvlottery.state.gov.* The Department of State does not send selectee notifications or letters by regular postal mail or by email. Any email notification or mailed letter stating that you have been selected to receive a DV does not come from the Department of State and is not legitimate. Any email communication you receive from the Department of State will direct you to review Entrant Status Check for new information about your application. The Department of State will never ask you to send money by mail or by services such as Western Union.

All entries received from each region are individually numbered, and at the end of the entry period, a computer will randomly select entries from among all the entries received for each geographic region. Within each region, the first entry randomly selected will be the first case registered; the second entry selected will be the second case registered, etc. All entries received within each region during the entry period will have an equal chance of being selected. When an entry has been selected, the entrant will receive notification of his or her selection through the Entrant Status Check available starting May 2, 2017, on the E–DV Web site *dvlottery.state.gov.* If you are selected and you respond to the instructions provided online via Entrant Status Check, the Department of State's Kentucky Consular Center (KCC) will process your case until you are instructed to appear for a visa interview at a U.S. Embassy or Consulate or, if you are in the United States, until you adjust status apply with USCIS in the United States.

29. I am already in the United States. If selected, may I adjust my status with USCIS?

Yes, provided you are otherwise eligible to adjust status under the terms of Section 245 of the Immigration and Nationality Act (INA), you may apply to USCIS for adjustment of status to permanent resident. You must ensure that USCIS can complete action on your case, including processing of any overseas spouse or children under 21 years of age, before September 30, 2018, since on that date your eligibility for the DV–2018 program expires. The Department of State will not approve any visa numbers or adjustments of status for the DV–2018 program after midnight EDT on September 30, 2018, under any circumstances.

30. If I am selected, for how long am I entitled to apply for a diversity visa?

If you are selected in the DV–2018 program, you are entitled to apply for visa issuance only during U.S. Government Fiscal Year 2018, which spans from October 1, 2017, through September 30, 2018. We encourage selectees to apply for visas as early as possible, once their lottery rank numbers become eligible for further processing.

Without exception, all selected and eligible applicants must obtain their visa or adjust status by the end of the fiscal year. There is no carry-over of DV benefits into the next year for persons who are selected but who do not obtain visas by September 30, 2018 (the end of the fiscal year). Also, spouses and children who derive status from a DV–2018 registration can only obtain visas in the DV category between October 1, 2017 and September 30, 2018. Applicants who apply overseas will receive an appointment notification from the Department through Entrant Status Check on the E–DV Web site four to six weeks before the scheduled appointment.

31. If a DV selectee dies, what happens to the case?

If a DV selectee dies at any point before he or she has traveled to the United States or adjusted status, the DV case is automatically terminated. Any derivative spouse and/or children of the deceased selectee will no longer be entitled to a DV visa. Any visas that were issued to them will be revoked.

Fees

32. How much does it cost to enter the E–DV Program?

There is no fee charged for submitting an electronic entry. However, if you are selected and apply for a Diversity Visa, you must pay all required visa application fees at the time of visa application and interview directly to the consular cashier at the U.S. Embassy or Consulate. If you are a selectee already in the United States and you apply to USCIS to adjust status, you will pay all required application fees directly to USCIS. If you are selected, you will receive details of required DV and immigrant visa application fees with the instructions provided through the E–DV Web site at *dvlottery.state.gov.*

33. How and where do I pay DV and immigrant visa fees if I am selected?

If you are a randomly selected entrant, you will receive instructions for the DV visa application process through Entrant Status Check at *dvlottery.state.gov.* You will pay all DV and immigrant visa application fees in person only at the U.S. Embassy or Consulate at the time of the visa application. The consular cashier will immediately give you a U.S. government receipt for payment. Do not send money for DV fees to anyone through the mail, Western Union, or any other delivery service if you are applying for an immigrant visa at a U.S. Embassy or Consulate.

If you are selected and you are already present in the United States and plan to file for adjustment of status with USCIS, the instructions page accessible through Entrant Status Check at *dvlottery.state.gov* contains separate instructions on how to mail adjustment of status application fees to a U.S. bank.

34. If I apply for a DV, but don't qualify to receive one, can I get a refund of the visa fees I paid?

No. Visa application fees cannot be refunded. You must meet all qualifications for the visa as detailed in these instructions. If a consular officer determines you do not meet requirements for the visa, or you are otherwise ineligible for the DV under U.S. law, the officer cannot issue a visa and you will forfeit all fees paid.

Ineligibilities

35. As a DV applicant, can I receive a waiver of any grounds of visa ineligibility? Does my waiver application receive any special processing?

DV applicants are subject to all grounds of ineligibility for immigrant visas specified in the Immigration and Nationality Act (INA). There are no special provisions for the waiver of any ground of visa ineligibility aside from those ordinarily provided in the INA, nor is there special processing for waiver requests. Some general waiver provisions for people with close relatives who are U.S. Citizens or Lawful Permanent Resident aliens may be available to DV applicants in some cases, but the time constraints in the DV program may make it difficult for applicants to benefit from such provisions.

DV Fraud Warning and Scams

36. How can I report Internet fraud or unsolicited email?

Please visit the *econsumer.gov* Web site, hosted by the Federal Trade Commission in cooperation with consumer-protection agencies from 17 nations. You may also report fraud to the Federal Bureau of Investigation (FBI) Internet Crime Complaint Center. To file a complaint about unsolicited email, visit the Department of Justice Contact Us page.

DV Statistics

37. How many visas will be issued in DV–2018?

By law, a maximum of 55,000 visas are available each year to eligible persons. However, in November 1997, the U.S. Congress passed the Nicaraguan Adjustment and Central American Relief Act (NACARA), which stipulates that beginning as early as DV–1999, and for as long as necessary, up to 5,000 of the 55,000 annually-allocated DVs will be made available for use under the NACARA program. The actual reduction of the limit began with DV–2000 and will remain in effect through the DV–2018 program, so 50,000 visas remain for the DV program described in these instructions.

38. If I receive a visa through the DV program, will the U.S. Government pay for my airfare to the United States, help me find housing and employment, and/or provide healthcare or any subsidies until I am fully settled?

No. The U.S. government will not provide any of these services to you if you receive a visa through the DV program. If you are selected to apply for a DV, you will need to demonstrate that you will not become a public charge in the United States before being issued a visa. This evidence may be in the form of a combination of your personal assets, an Affidavit of Support (Form I–134) submitted by a relative or friend residing in the United States, an offer of employment from an employer in the United States, or other evidence.

List of Countries/Areas by Region Whose Natives Are Eligible for DV–2018

The list below shows the countries whose natives are eligible for DV–2018, grouped by geographic region. Dependent areas overseas are included within the region of the governing country. USCIS identified the countries whose natives are not eligible for the DV–2018 program according to the formula in Section 203(c) of the INA. The countries whose natives are not eligible for the DV program (because they are the principal source countries of Family-Sponsored and Employment-Based immigration or "high-admission" countries) are noted after the respective regional lists.

Africa

Algeria
Angola
Benin
Botswana
Burkina Faso
Burundi
Cameroon
Cabo Verde
Central African Republic
Chad
Comoros
Congo
Congo, Democratic Republic of the
Cote D'Ivoire (Ivory Coast)
Djibouti
Egypt *
Equatorial Guinea
Eritrea
Ethiopia
Gabon
Gambia, The

Ghana
Guinea
Guinea-Bissau
Kenya
Lesotho
Liberia
Libya
Madagascar
Malawi
Mali
Mauritania
Mauritius
Morocco
Mozambique
Namibia
Niger
Rwanda
Sao Tome and Principe
Senegal
Seychelles
Sierra Leone
Somalia
South Africa
South Sudan
Sudan
Swaziland
Tanzania
Togo
Tunisia
Uganda
Zambia
Zimbabwe

* Persons born in the areas administered prior to June 1967 by Israel, Jordan, Syria, and Egypt are chargeable, respectively, to Israel, Jordan, Syria, and Egypt. Persons born in the Gaza Strip are chargeable to Egypt; persons born in the West Bank are chargeable to Jordan; persons born in the Golan Heights are chargeable to Syria.

In Africa, natives of Nigeria are not eligible for this year's diversity program.

Asia

Afghanistan
Bahrain
Bhutan
Brunei
Burma
Cambodia
Hong Kong Special Administrative Region **
Indonesia
Iran
Iraq
Israel *
Japan
Jordan *
Kuwait
Laos
Lebanon
Malaysia
Maldives
Mongolia
Nepal
North Korea
Oman
Qatar
Saudi Arabia
Singapore
Sri Lanka
Syria *
Taiwan **
Thailand
Timor-Leste
United Arab Emirates
Yemen

* Persons born in the areas administered prior to June 1967 by Israel, Jordan, Syria, and Egypt are chargeable, respectively, to Israel, Jordan, Syria, and Egypt. Persons born in the Gaza Strip are chargeable to Egypt; persons born in the West Bank are chargeable to Jordan; persons born in the Golan Heights are chargeable to Syria.

** For the purposes of the diversity program only, persons born in Macau S.A.R. derive eligibility from Portugal, and must select Portugal as their country of eligibility.

Natives of the following Asia Region countries are not eligible for this year's diversity program: Bangladesh, China (mainland-born), India, Pakistan, South Korea, Philippines, and Vietnam. Hong Kong S.A.R. (Asia region), Macau S.A.R. (Europe region, chargeable to Portugal), and Taiwan (Asia region) do qualify and are listed here.

Europe

Albania
Andorra
Armenia
Austria
Azerbaijan
Belarus
Belgium
Bosnia and Herzegovina
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark (including components and dependent areas overseas)
Estonia
Finland
France (including components and areas overseas)
Georgia
Germany
Greece
Hungary
Iceland
Ireland
Italy
Kazakhstan
Kosovo
Kyrgyzstan
Latvia
Liechtenstein
Lithuania
Luxembourg
Macau Special Administrative Region **
Macedonia
Malta
Moldova
Monaco
Montenegro
Netherlands (including components and dependent areas overseas)
Northern Ireland **
Norway (including components and dependent areas overseas)
Poland
Portugal (including components and dependent areas overseas)
Romania
Russia
San Marino
Serbia
Slovakia
Slovenia
Spain
Sweden
Switzerland
Tajikistan
Turkey
Turkmenistan
Ukraine
Uzbekistan
Vatican City

** Macau S.A.R. does qualify and is listed above. For the purposes of the diversity program only, persons born in Macau S.A.R. derive eligibility from Portugal, and must select Portugal as their country of eligibility.

Natives of the following European countries are not eligible for this year's DV program: Great Britain (United Kingdom). Great Britain (United Kingdom) includes the following dependent areas: Anguilla, Bermuda, British Virgin Islands, British Indian Ocean Territory, Cayman Islands, Falkland Islands, Gibraltar, Montserrat, Pitcairn, South Georgia and the South Sandwich Islands, St. Helena, and Turks and Caicos Islands. Note that for purposes of the diversity program only, Northern Ireland is treated separately; Northern Ireland does qualify and is listed among the qualifying areas.

North America

The Bahamas

In North America, natives of Canada and Mexico are not eligible for this year's diversity program.

Oceania

Australia (including components and dependent areas overseas)
Fiji
Kiribati
Marshall Islands
Micronesia, Federated States of
Nauru
New Zealand (including components and dependent areas overseas)
Palau

Papua New Guinea
Samoa
Solomon Islands
Tonga
Tuvalu
Vanuatu

South America, Central America, and the Caribbean

Antigua and Barbuda
Argentina
Barbados
Belize
Bolivia
Chile
Costa Rica
Cuba
Dominica
Ecuador
Grenada
Guatemala
Guyana
Honduras
Nicaragua
Panama
Paraguay
Saint Kitts and Nevis
Saint Lucia
Saint Vincent and the Grenadines
Suriname
Trinidad and Tobago
Uruguay
Venezuela

Countries in this region whose natives are not eligible for this year's diversity program: Brazil, Colombia, Dominican Republic, El Salvador, Haiti, Jamaica, Mexico, and Peru.

Authority: 22 CFR 42.33(b)(3), implementing sections 201(a)(3), 201(e), 203(c), and 204(a)(1)(I) of the Immigration and Nationality Act, as amended, (8 U.S.C. 1151, 1153, and 1154(a)(1)(I)).

Dated: August 31, 2016.

David T. Donahue,

Acting Assistant Secretary, Bureau of Consular Affairs, Department of State.

[FR Doc. 2016–22217 Filed 9–15–16; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF STATE

[Public Notice: 9718]

Culturally Significant Objects Imported for Exhibition Determinations: "The Rama Epic: Hero, Heroine, Ally, Foe" Exhibition

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition "The Rama Epic: Hero, Heroine, Ally, Foe," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Asian Art Museum of San Francisco, San Francisco, California, from on or about October 21, 2016, until on or about January 15, 2017, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: September 8, 2016.

Mark Taplin,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2016–22372 Filed 9–15–16; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 9719]

Culturally Significant Objects Imported for Exhibition Determinations: "Word and Image: Martin Luther's Reformation" Exhibition

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition "Word and Image: Martin Luther's Reformation," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Morgan Library & Museum, New York, New York, from on or about October 7, 2016, until on or about January 22, 2017, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: September 8, 2016.

Mark Taplin,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2016–22378 Filed 9–15–16; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 9721]

Notice of Public Meeting in Preparation for the Sixty-Sixth Session of the International Maritime Organization Technical Cooperation Committee

The Department of State will conduct an open meeting at 9:00 a.m. on October 6, 2016, in Room 5L18–01 of the Douglas A. Munro Coast Guard Headquarters Building at St. Elizabeth's, 2703 Martin Luther King Jr. Avenue SE., Washington, DC 20593. The primary purpose of the meeting is to prepare for the sixty-sixth session of the International Maritime Organization's (IMO) Technical Cooperation Committee to be held at the IMO Headquarters, United Kingdom, October 10–12, 2016.

The agenda items to be considered include:

—Integrated Technical Cooperation Programme: Annual Report for 2015
—Sustainable financing of the Integrated Technical Cooperation Programme
—The 2030 Agenda for Sustainable Development
  (a) Maritime policy development
  (b) Country Maritime Profiles
  (c) Linkage between the ITCP and the Sustainable Development Goals

(d) Revision of the Assembly resolutions relating to technical cooperation
—Partnerships:
(a) Regional presence and coordination
(b) Partnership arrangements
—Voluntary IMO Member Audit Scheme and IMO Member States Audit Scheme
—Capacity building: Strengthening the impact of women in the maritime sector
—Global maritime training institutions
—Impact Assessment Exercise for the period of 2012–2015

Members of the public may attend this meeting up to the seating capacity of the room. Upon request to the meeting coordinator, members of the public may also participate via teleconference. To facilitate the building security process, and to request reasonable accommodation, those who plan to attend should contact the meeting coordinator, LCDR Tiffany Duffy, by email at *imo@uscg.mil,* by phone at (202) 372–1376, or in writing at 2703 Martin Luther King Jr. Ave. SE., Stop 7509, Washington, DC 20593–7509 not later than September 29. Requests made after September 29, 2016 might not be able to be accommodated. Please note that due to security considerations, two valid, government issued photo identifications must be presented to gain entrance to the Coast Guard Headquarters Building. The Coast Guard Headquarters Building is accessible by taxi, public transportation, and privately owned conveyance (upon request). Additional information regarding this and other IMO public meetings may be found at: *www.uscg.mil/imo.*

Dated: September 7, 2016.

Jonathan W. Burby,

Coast Guard Liaison Officer, Office of Ocean and Polar Affairs, Department of State.

[FR Doc. 2016–22381 Filed 9–15–16; 8:45 am]

BILLING CODE 4710–09–P

SURFACE TRANSPORTATION BOARD

[Docket No. MCF 21072]

National Express LLC—Acquisition Of Control—New Dawn Transit, Llc

AGENCY: Surface Transportation Board.

ACTION: Notice tentatively approving and authorizing finance transaction.

SUMMARY: On August 17, 2016, National Express LLC (National Express or Applicant), a non-carrier, filed an application under 49 U.S.C. 14303 to acquire control of New Dawn Transit, LLC (New Dawn). The Board is tentatively approving and authorizing the transaction, and, if no opposing comments are timely filed, this notice will be the final Board action. Persons wishing to oppose the application must follow the rules at 49 CFR 1182.5 & 1182.8.

DATES: Comments must be filed by October 31, 2016. Applicant may file a reply by November 15, 2016. If no opposing comments are filed by October 31, 2016, this notice shall be effective on November 1, 2016.

ADDRESSES: Send an original and 10 copies of any comments referring to Docket No. MCF 21072 to: Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, send one copy of comments to Applicant's representative: Andrew K. Light, Scopelitis, Garvin, Light, Hanson & Feary, P.C., 10 W. Market Street, Suite 1500, Indianapolis, IN 46204.

FOR FURTHER INFORMATION CONTACT: Nathaniel Bawcombe (202) 245–0376. Federal Information Relay Service (FIRS) for the hearing impaired: 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Applicant, a non-carrier, states that it is a holding company organized under the laws of the state of Delaware that is indirectly controlled by a British corporation, National Express Group, PLC (Express Group). Applicant states that Express Group indirectly controls the following passenger motor carriers (National Express Affiliated Carriers): Beck Bus Transportation Corp. (Beck); Carrier Management Corporation (CMI); Durham School Services, L.P. (Durham); Folmsbee's Transportation Inc. (Folmsbee); MV Student Transportation, Inc. (MV); National Express Transit Corporation (NETC); National Express Transit Services Corporation (NETSC); Petermann Ltd. (LTD); Petermann Northeast LLC (Northeast); Petermann Northwest LLC (Northwest); Petermann Southwest LLC (Southwest); Petermann STSA, LLC (STSA); The Provider Enterprises, Inc. (Provider); Rainbow Management Service Inc. (Rainbow); Safeway Training and Transportation Services Inc. (Safeway); Septran, Inc. (Septran); Smith Bus Service, Inc. (Smith); Suburban Paratransit Service, Inc. (Suburban Paratransit); Trans Express, Inc. (Trans Express); and White Plains Bus Company, Inc. (White Plains).

Applicant alleges the following facts regarding the National Express Affiliated Carriers held by Express Group:

- Beck is a passenger motor carrier primarily engaged in providing student school bus transportation services in the states of Illinois and Indiana under contracts with regional and local school jurisdictions. Beck also provides charter passenger services to the public (MC–143528).
- CMI is a passenger motor carrier doing business as Matthews Bus Company and is primarily engaged in providing student school bus transportation services in the state of Pennsylvania under contracts with regional and local school jurisdictions. CMI also provides intrastate charter passenger services to the public.
- Durham is a passenger motor carrier primarily engaged in providing student school bus transportation services in approximately 32 states under contracts with regional and local school jurisdictions. Durham also provides charter passenger services to the public (MC–163066).
- Folmsbee is a passenger motor carrier primarily engaged in providing unregulated student school bus transportation services in the state of New York under contracts with regional and local school jurisdictions (MC–818630).
- MV is a passenger motor carrier primarily engaged in providing student school bus transportation services in the state of Missouri under contracts with regional and local school jurisdictions. MV also provides charter passenger services to the public (MC–148934).
- NETC is an intrastate passenger motor carrier with its principal place of business in Cincinnati, Ohio.
- NETSC is a passenger motor carrier engaged primarily in providing intrastate transit services in the areas of Westmoreland, Pa.; Arlington, Va.; Greensboro, N.C.; Vallejo, Cal.; and Yuma, Ariz.
- LTD is a passenger motor carrier primarily engaged in providing non-regulated school bus transportation services in the state of Ohio under contracts with regional and local school jurisdictions. LTD also provides charter passenger services to the public (MC–364668).
- Northeast is a passenger motor carrier primarily engaged in providing student school bus transportation services, primarily in the states of Ohio and Pennsylvania under contracts with regional and local school jurisdictions. Northeast also provides charter passenger services to the public (MC–723926).
- Northwest is a passenger motor carrier primarily engaged in providing non-regulated school bus transportation services under contracts with regional and local school jurisdictions.
- Southwest is a passenger motor carrier primarily engaged in providing

student school bus transportation services in the state of Texas under contracts with regional and local school jurisdictions. In addition to its core school bus services, Southwest also provides charter passenger services to the public (MC–644996).

- STSA is a passenger motor carrier primarily engaged in providing student school bus transportation services, primarily in the state of Kansas under contracts with regional and local school jurisdictions. STSA also provides charter passenger services to the public (MC–749360).
- Provider is a passenger motor carrier doing business as Provider Bus, and is primarily engaged in providing non-regulated school bus transportation services in the state of New Hampshire under contracts with regional and local school jurisdictions.
- Rainbow provides interstate and intrastate charter and special party passenger transportation services in the state of New York (MC–490015).
- Safeway is a passenger motor carrier primarily engaged in providing non-regulated school bus transportation services in the state of New Hampshire under contracts with regional and local school jurisdictions (MC–522039).
- Septran is a passenger motor carrier primarily engaged in providing non-regulated school bus transportation services in the state of Illinois under contracts with regional and local school jurisdictions (MC–795208).
- Smith is a passenger motor carrier primarily engaged in providing non-regulated school bus transportation services in the state of Maryland and surrounding areas under contracts with regional and local school jurisdictions.
- Suburban Paratransit is a motor carrier providing paratransit services primarily in Westchester County and Bronx, NY.
- Trans Express provides interstate and intrastate passenger transportation services in the state of New York (MC–187819).
- White Plains is a passenger motor carrier that operates primarily as a provider of non-regulated school bus transportation services in the State of New York. White Plains also operates as a motor passenger carrier providing charter service to the public (MC–160624).

Applicant states that New Dawn is a New York limited liability company that holds authority from the Federal Motor Carrier Safety Administration as a motor carrier of passengers (MC–932702). Applicant explains that all of the issued and outstanding membership equity interest of New Dawn is owned and held by Indra Fouche, an individual (the Seller). Applicant further states that the Seller has no direct or indirect ownership interest in any other interstate passenger motor carrier.

According to Applicant, New Dawn operates primarily as a provider of non-regulated school bus transportation services, transporting children to and from school throughout the metropolitan area of New York City. Applicant adds that New Dawn maintains a fleet of 140 buses and has approximately 154 drivers, and that it also operates as a motor passenger carrier providing charter service to the public using its fleet of buses.

Applicant explains that National Express would assume direct 100 percent control of New Dawn through the membership ownership.

Under 49 U.S.C. 14303(b), the Board must approve and authorize a transaction that it finds consistent with the public interest, taking into consideration at least: (1) The effect of the proposed transaction on the adequacy of transportation to the public; (2) the total fixed charges that result; and (3) the interest of affected carrier employees. Applicant submitted information, as required by 49 CFR 1182.2, including information to demonstrate that the proposed transaction is consistent with the public interest under 49 U.S.C. 14303(b), and a statement that the aggregate gross operating revenues of the National Express Affiliated Carriers and New Dawn exceeded $2 million for the preceding 12-month period. *See* 49 U.S.C. 14303(g).[1]

Applicant submits that the proposed transaction would have no significant impact on the adequacy of transportation services to the public, as New Dawn would continue to provide the services it currently provides using the same names for the foreseeable future. Applicant states that New Dawn "will continue to operate, but going forward, it will be operating within the National Express corporate family, an organization already thoroughly experienced in passenger transportation operations." (Appl. 12.)

Applicant states that "[t]he addition of [New Dawn] to the carriers held by National Express is consistent with the practices within the passenger motor carrier industry of strong, well-managed transportation organizations adapting their corporate structure to operate several different passenger carriers within the same market, but in different geographic areas." (*Id.*) Applicant asserts that New Dawn is experienced in some of the same market segments already served by some of the National Express Affiliated Carriers. Applicant expects the transaction to result in operating efficiencies and cost savings derived from economies of scale, all of which would help to ensure the provision of adequate service to the public.

Applicant further asserts that the acquisition of New Dawn would serve to enhance the viability of the overall National Express organization and the operations of the National Express Affiliated Carriers, which would ensure the continued availability of adequate passenger transportation service for the public. (*Id.*)

Applicant also claims that neither competition nor the public interest would be adversely affected. Applicant states that New Dawn is a relatively small carrier in the overall markets in which it competes: Unregulated metropolitan school bus operations, and provider of charter services. Applicant states that school bus operators typically occupy a limited portion of the charter business because (i) the equipment offered is not as comfortable as that offered by motor coach operators; and (ii) scheduling demands imposed by the primary school bus operation impose major constraints on charter services that can be offered. It further explains that the charter services offered by New Dawn are geographically dispersed from those of the National Express Affiliated Carriers, and that there is limited overlap in service areas and/or in customer bases among the National Express Affiliated Carriers and New Dawn. Thus, Applicant states that the impact of the contemplated transaction on the regulated motor carrier industry would be minimal at most and that neither competition nor the public interest would be adversely affected.

Applicant asserts that there are no fixed charges associated with the contemplated transaction. Applicant also states that it does not anticipate a measurable reduction in force or changes in compensation levels and/or benefits to employees. Applicant submits, however, that staffing redundancies could potentially result in limited downsizing of back-office or managerial level personnel.

The Board finds that the acquisition proposed in the application is consistent with the public interest and should be tentatively approved and authorized. If any opposing comments are timely filed, these findings will be deemed vacated, and, unless a final decision can be made on the record as developed, a procedural schedule will be adopted to reconsider the application. *See* 49 CFR 1182.6(c). If no opposing comments are filed by the expiration of the comment period, this notice will take effect automatically and will be the final Board action.

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[1] Applicants with gross operating revenues exceeding $2 million are required to meet the requirements of 49 CFR 1182.

This action is categorically excluded from environmental review under 49 CFR 1105.6(c).

Board decisions and notices are available on our Web site at *WWW.STB.GOV.*

It is ordered:

1. The proposed transaction is approved and authorized, subject to the filing of opposing comments.

2. If opposing comments are timely filed, the findings made in this notice will be deemed vacated.

3. This notice will be effective November 1, 2016, unless opposing comments are filed by October 31, 2016.

4. A copy of this notice will be served on: (1) The U.S. Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; (2) the U.S. Department of Justice, Antitrust Division, 10th Street & Pennsylvania Avenue NW., Washington, DC 20530; and (3) the U.S. Department of Transportation, Office of the General Counsel, 1200 New Jersey Avenue SE., Washington, DC 20590.

Decided: September 12, 2016.

By the Board, Chairman Elliott, Vice Chairman Miller, and Commissioner Begeman.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2016–22283 Filed 9–15–16; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Opportunity for Public Comment on Land Use Change From Aeronautical to Non-Aeronautical Use at Hanscom Field in Bedford, MA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Request for public comments.

SUMMARY: Under the provisions of Title 49, U.S.C. 47153(d), notice is being given that the FAA is considering a request from the Massachusetts Port Authority (MPA) in East Boston, MA, to waive the surplus property requirements for approximately 7.1 acres of airport property located at Hanscom Field in Bedford, MA.

The subject parcel has been identified for commercial development and MPA will negotiate a long term lease to generate non-aviation revenue for the airport. As such, MPA is requesting a release to change the property from aeronautical use to non-aeronautical use. It has been determined through study and master planning that the subject parcel will not be needed for future aeronautical purposes. Further, the parcel of land is separated by a road and not contiguous to the airport proper. Full and permanent relief of the surplus property requirements on this parcel will allow the airport to generate long term revenue through lease of the land. All lease revenue will continue to be subject to the FAAs revenue-use policy and dedicated to the maintenance and operation of Hanscom Field.

DATES: Comments must be received on or before October 17, 2016.

ADDRESSES: You may send comments using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov,* and follow the instructions on providing comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Interested persons may inspect the request and supporting documents by contacting the FAA at the address listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Mr. Jorge E. Panteli, Compliance and Land Use Specialist, Federal Aviation Administration New England Region Airports Division, 1200 District Avenue, Burlington, Massachusetts, Telephone 781–238–7618.

Issued in Burlington, Massachusetts, on September 6, 2016.

Mary T. Walsh,

Manager, Airports Division.

[FR Doc. 2016–22137 Filed 9–15–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Sixteenth RTCA SC–209 Working Session and Plenary Session Joint With EUROCAE WG 49, WG 51, and RTCA SC–186

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Sixteenth RTCA SC–209 Working Session and Plenary Session joint with EUROCAE WG 49, WG 51, and RTCA SC–186.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of Sixteenth RTCA SC–209 Working Session and Plenary Session joint with EUROCAE WG 49, WG 51, and RTCA SC–186.

DATES: The meeting will be held October 17–21, 2016, 09:00 a.m.–04:30 p.m.

ADDRESSES: The meeting will be held at: RTCA Headquarters, 1150 18th Street NW., Suite 910, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Al Secen at *asecen@rtca.org* or 202–330–0647, or The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. App.), notice is hereby given for a meeting of the Sixteenth RTCA SC–209 Working Session and Plenary Session joint with EUROCAE WG 49, WG 51, and RTCA SC–186. The agenda will include the following:

Monday, October 17th, WG–1 Mode S Transponder MOPS Development
Tuesday, October 18th, WG–1 Mode S Transponder MOPS Development
Wednesday, October 19th, WG–1 Mode S Transponder MOPS Development
Thursday, October 20th, WG–1 Mode S Transponder MOPS Development
Friday, October 21st, Plenary Session (9:00 a.m.–Noon)

1. Host and Co-Chairs Welcome, Introductions, and Remarks
2. Review of Meeting Agenda
3. Review and Approval of the Minutes from Meeting #15 of SC–209
4. WG–1—ATCRBS/Mode S Transponder
   - ▪ Status of MOPS Revisions
5. EUROCAE WG–49—SSR Mode S Transponders
   - ▪ Status of MOPS Revisions
   - ▪ Update on European Activity
6. Other Business
7. Date, Place, and Time of Future Meetings
8. Review of Action Items
9. Adjournment

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on September 13, 2016.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG–A17 NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2016–22405 Filed 9–15–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Commercial Space Transportation Advisory Committee—Open Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Commercial Space Transportation Advisory Committee open meeting.

SUMMARY: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. App. 2), notice is hereby given of a meeting of the Commercial Space Transportation Advisory Committee (COMSTAC). The meeting will take place on Tuesday, October 25, 2016, from 1:00 p.m. to 5:00 p.m., and Wednesday, October 26, 2016 from 8:00 a.m. to 5:00 p.m. at the National Transportation Safety Board Conference Center, 429 L'Enfant Plaza SW., Washington, DC 20594. This will be the 64th meeting of the COMSTAC.

The proposed schedule for the COMSTAC working group meetings on October 25th and 26th is below:

—International Space Policy (Oct 25 1:00 p.m.–3:00 p.m.)
—Business/Legal (Oct 25 3:00 p.m.–5:00 p.m.)
—Standards (Oct 26 8:00 a.m.–10:00 a.m.)
—Operations (Oct 26 10:00 a.m.–12:00 p.m.)

The full Committee will meet on October 26, from 1:00 p.m. to 5:00 p.m. The proposed agenda for that meeting features speakers relevant to the commercial space transportation industry; and reports and recommendations from the working groups.

Interested members of the public may submit relevant written statements for the COMSTAC members to consider under the advisory process. Statements may concern the issues and agenda items mentioned above and/or additional issues that may be relevant for the U.S. commercial space transportation industry. Interested parties wishing to submit written statements should contact Michael Beavin, COMSTAC Executive Director, (the contact person listed below) and Designated Federal Officer in writing (mail or email) by October 14, 2016, so that the information can be made available to COMSTAC members for their review and consideration before the October 25–26, 2016 meeting. Written statements should be supplied in the following formats: one hard copy with original signature and/or one electronic copy via email.

An agenda will be posted on the FAA Web site at *www.faa.gov/go/ast.* For specific information concerning the times and locations of the COMSTAC working group meetings, contact the contact person listed below.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the contact person listed below in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Michael Beavin, telephone (202) 267–9051; email *Michael.beavin@faa.gov,* FAA Office of Commercial Space Transportation, 800 Independence Avenue SW., Room 331, Washington, DC 20591.

Complete information regarding COMSTAC is available on the FAA Web site at: *http://www.faa.gov/about/office_org/headquarters_offices/ast/advisory_committee/.*

Issued in Washington, DC, on September 8, 2016.

George C. Nield,

Associate Administrator for Commercial Space Transportation.

[FR Doc. 2016–22136 Filed 9–15–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Opportunity for Public Comment for Land Exchange at New Bedford Airport in New Bedford, MA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Request for public comments.

SUMMARY: Under the provisions of Title 49, U.S.C. 47153(d), notice is being given that the FAA is considering a request from New Bedford Airport in New Bedford, MA, to exchange .65 acres of airport land for 1.14 acres of land owned by the Tifereth Israel Congregation in order to construct the Runway Safety Area and provide for a maintenance/emergency road for Runway 14–32 at New Bedford Airport in New Bedford, MA.

The .65 acres of airport land being exchanged by the airport is not required for current of future aviation use. The land is remote, non-contiguous to the airport land and is primarily wooded. The two parcels that will be acquired from Tifereth Israel Congregation will be used to meet FAA design requirements for the Runway 14 Runway Safety Area and provide a maintenance/emergency access road for this runway end.

DATES: Comments must be received on or before October 17, 2016.

ADDRESSES: You may send comments using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov,* and follow the instructions on providing comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Interested persons may inspect the request and supporting documents by contacting the FAA at the address listed under **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: Mr. Jorge E. Panteli, Compliance and Land Use Specialist, Federal Aviation Administration New England Region Airports Division, 1200 District Avenue, Burlington, Massachusetts, Telephone 781–238–7618.

Issued in Burlington, Massachusetts, on September 6, 2016.

Mary T. Walsh,

Manager, Airports Division.

[FR Doc. 2016–22138 Filed 9–15–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Buy America Waiver Notification

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice.

SUMMARY: This notice provides information regarding FHWA's finding that a Buy America waiver is appropriate for the use of non-domestic iron and steel components of electric vehicle DC fast charging stations with

maximum power (50 kw), voltage range (200–500 VDC), and current output (165 ADC) in the State of Massachusetts.

DATES: The effective date of the waiver is September 19, 2016.

FOR FURTHER INFORMATION CONTACT: For questions about this notice, please contact Mr. Gerald Yakowenko, FHWA Office of Program Administration, (202) 366–1562, or via email at *gerald.yakowenko@dot.gov*. For legal questions, please contact Mr. William Winne, FHWA Office of the Chief Counsel, 202–366–1397, or via email at *William.Winne@dot.gov*. Office hours for the FHWA are from 8:00 a.m. to 4:30 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded from the **Federal Register**'s home page at: *http://www.archives.gov* and the Government Printing Office's database at: *http://www.access.gpo.gov/nara*.

Background

The FHWA's Buy America policy in 23 CFR 635.410 requires a domestic manufacturing process for any steel or iron products (including protective coatings) that are permanently incorporated in a Federal-aid construction project. The regulation also provides for a waiver of the Buy America requirements when the application would be inconsistent with the public interest or when satisfactory quality domestic steel and iron products are not sufficiently available. This notice provides information regarding FHWA's finding that a Buy America waiver is appropriate for use of non-domestic iron and steel components of electric vehicle DC fast charging stations with maximum power (50 kw), voltage range (200–500 VDC) and current output (165 ADC) in the State of Massachusetts.

In accordance with Division K, section 122 of the "Consolidated and Further Continuing Appropriations Act, 2015" (Pub. L. 113–235), FHWA published a notice of intent to issue a waiver on its Web site: *http://www.fhwa.dot.gov/construction/contracts/waivers.cfm?id=129* on June 16th. The FHWA received no comments in response to the publication. Based on all the information available to the agency, FHWA concludes that there are no domestic manufacturers of iron and steel components compatible with electric vehicle DC fast charging stations with maximum power (50 kw), voltage range (200–500 VDC) and current output (165 ADC) that meets the grant requirements.

In accordance with the provisions of section 117 of the SAFETEA–LU Technical Corrections Act of 2008 (Pub. L. 110–244, 122 Stat. 1572), FHWA is providing this notice as its finding that a waiver of Buy America requirements is appropriate. The FHWA invites public comment on this finding for an additional 15 days following the effective date of the finding. Comments may be submitted to FHWA's Web site via the link provided to the waiver page noted above.

(Authority: 23 U.S.C. 313; Pub. L. 110–161, 23 CFR 635.410)

Issued on: August 29, 2016.

Gregory G. Nadeau,

Administrator, Federal Highway Administration.

[FR Doc. 2016–22305 Filed 9–15–16; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Buy America Waiver Notification

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice provides information regarding FHWA's finding that a Buy America waiver is appropriate for the obligation of Federal-aid funds for 21 State projects involving the acquisition of vehicles and equipment on the condition that they be assembled in the U.S.

DATES: The effective date of the waiver is September 19, 2016.

FOR FURTHER INFORMATION CONTACT: For questions about this notice, please contact Mr. Gerald Yakowenko, FHWA Office of Program Administration, 202–366–1562, or via email at *gerald.yakowenko@dot.gov*. For legal questions, please contact Mr. William Winne, FHWA Office of the Chief Counsel, 202–366–1397, or via email at *William.Winne@dot.gov*. Office hours for the FHWA are from 8:00 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded from the **Federal Register**'s home page at *http://www.archives.gov* and the Government Printing Office's database at *http://www.access.gpo.gov/nara*.

Background

This notice provides information regarding FHWA's finding that a Buy America waiver is appropriate for the obligation of Federal-aid funds for 21 State projects involving the acquisition of vehicles (including sedans, vans, pickups, trucks, buses, and street sweepers) and equipment (such as trail grooming equipment) on the condition that they be assembled in the U.S. The waiver would apply to approximately 796 vehicles and equipment acquisitions. The requests for the second quarter of calendar year 2016, available at *http://www.fhwa.dot.gov/construction/contracts/cmaq160713.cfm*, are incorporated by reference into this notice. These projects are being undertaken to implement air quality improvement, safety, and mobility goals under FHWA's Congestion Mitigation and Air Quality Improvement Program and the Recreational Trails Program.

Title 23, Code of Federal Regulations, section 635.410 requires that steel or iron materials (including protective coatings) that will be permanently incorporated in a Federal-aid project must be manufactured in the U.S. For FHWA, this means that all the processes that modified the chemical content, physical shape or size, or final finish of the material (from initial melting and mixing, continuing through the bending and coating) occurred in the U.S. The statute and regulations create a process for granting waivers from the Buy America requirements when its application would be inconsistent with the public interest or when satisfactory quality domestic steel and iron products are not sufficiently available. In 1983, FHWA determined that it was both in the public interest and consistent with the legislative intent to waive Buy America for manufactured products other than steel manufactured products. However, FHWA's national waiver for manufactured products does not apply to the requests in this notice because they involve predominately steel and iron manufactured products. The FHWA's Buy America requirements do not have special provisions for applying Buy America to "rolling stock" such as vehicles or vehicle components (see 49 U.S.C. 5323(j)(2)(C), 49 CFR 661.11, and 49 U.S.C. 24405(a)(2)(C) for examples of Buy America rolling stock provisions for other DOT agencies).

Based on all the information available to the agency, FHWA concludes that there are no domestic manufacturers that produce the vehicles and vehicle components identified in this notice in such a way that their steel and iron elements are manufactured domestically. The FHWA's Buy America requirements were tailored to the types of products that are typically used in highway construction, which generally meet the requirement that steel and iron materials be manufactured domestically. In today's global industry, vehicles are assembled with iron and steel components that are manufactured all over the world. The FHWA is not aware of any domestically produced vehicle on the market that meets FHWA's Buy America requirement to have all its iron and steel be manufactured exclusively in the U.S. For example, the Chevrolet Volt, which was identified by many commenters in a November 21, 2011, **Federal Register** Notice (76 FR 72027) as a car that is made in the U.S., is comprised of only 45 percent of U.S. and Canadian content according to the National Highway Traffic Safety Administration's Part 583 American Automobile Labeling Act Report Web page *(http://www.nhtsa.gov/Laws+&+Regulations/Part+583+American+Automobile+Labeling+Act+(AALA)+Reports)*. Moreover, there is no indication of how much of this 45 percent content is U.S.-manufactured (from initial melting and mixing) iron and steel content.

In accordance with Division K, section 122 of the "Consolidated and Further Continuing Appropriations Act, 2015" (Pub. L. 113–235), FHWA published a notice of intent to issue a waiver on its Web site at *http://www.fhwa.dot.gov/construction/contracts/waivers.cfm?id=131* on July 13th. The FHWA received five comments in response to the publication. Two commenters are in favor of the waiver. One commenter suggested that amendments should be made to use American made vehicles if possible. The other two commenters opposed the waiver without suggestions regarding domestic availability of the proposed vehicles and equipment project.

Based on FHWA's conclusion that there are no domestic manufacturers that can produce the vehicles and equipment identified in this notice in such a way that steel and iron materials are manufactured domestically, and after consideration of the comments received, FHWA finds that application of FHWA's Buy America requirements to these products is inconsistent with the public interest (23 U.S.C. 313(b)(1) and 23 CFR 635.410(c)(2)(i)). However, FHWA believes that it is in the public interest and consistent with the Buy America requirements to impose the condition that the vehicles and the vehicle components be assembled in the U.S. Requiring final assembly to be performed in the U.S. is consistent with past guidance to FHWA Division Offices on manufactured products (see Memorandum on Buy America Policy Response, Dec. 22, 1997, *http://www.fhwa.dot.gov/programadmin/contracts/122297.cfm*). A waiver of the Buy America requirement without any regard to where the vehicle is assembled would diminish the purpose of the Buy America requirement. Moreover, in today's economic environment, the Buy America requirement is especially significant in that it will ensure that Federal Highway Trust Fund dollars are used to support and create jobs in the U.S. This approach is similar to the conditional waivers previously given for various vehicle projects. Thus, so long as the final assembly of the 21 State projects occurs in the U.S., applicants to this waiver request may proceed to purchase these vehicles and equipment consistent with the Buy America requirement.

In accordance with the provisions of section 117 of the "Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users, Technical Corrections Act of 2008" (Pub. L. 110–244), FHWA is providing this notice of its finding that a public interest waiver of Buy America requirements is appropriate on the condition that the vehicles and equipment identified in the notice be assembled in the U.S. The FHWA invites public comment on this finding for an additional 15 days following the effective date of the finding. Comments may be submitted to FHWA's Web site via the link provided to the waiver page noted above.

Authority: 23 U.S.C. 313; P.L. 110–161, 23 CFR 635.410.

Issued on: August 29, 2016.

Gregory G. Nadeau,

Administrator, Federal Highway Administration.

[FR Doc. 2016–22301 Filed 9–15–16; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2016–0171]

Agency Information Collection Activities: Request for Comments; Renewal of an Information Collection(s): U.S. Department of Transportation, Individual Complaint of Employment Discrimination Form

AGENCY: Office of the Secretary, U.S. Department of Transportation.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, (44 U.S.C. 3501 *et seq.*), this notice announces the U.S. Department of Transportation's (DOT) intention to request the Office of Management and Budget's (OMB) approval for the utilization of the Individual Complaint of Employment Discrimination form when processing Equal Employment Opportunity (EEO) discrimination complaints filed by applicants for employment with DOT. The OMB approved the form in 2009 with its renewal required by September 30, 2012. Subsequently, DOT was given approval of the form until August 31, 2014. The renewal period then lapsed; therefore, the form expired. The OMB approved the form in 2015 with its renewal required by December 31, 2016.

DATES: Comments on this notice must be received by November 15, 2016.

ADDRESSES: You may submit comments [identified by Docket No. DOT–OST–2016–0171] by any of the following methods:

- *Fax:* 202–493–2064.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Room W12–140, Washington, DC 20590.
- *Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.

Instructions: All submissions must include the Agency name (Office of the Secretary, DOT) and docket number for this rulemaking. You should provide two copies of your comments if you submit them by mail or hand delivery. Note that all comments received will be posted without change to *www.regulations.gov,* including any personal information provided, and will be available to Internet users. You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477) or you may visit *htttp://DocketsInfo.dot.gov.*

Docket: For Internet access to the docket to read background documents and comments received, go to *www.regulations.gov.* Background documents and comments received may also be viewed at DOT, 1200 New Jersey Avenue SE., Docket Operations, West Building, Room W12–140, Washington, DC 25090, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Tami L. Wright, Associate Director, Compliance Operations Division (S–34), Departmental Office of Civil Rights, Office of the Secretary, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, 202–366–9370 or (TTY) 202–366–0663.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2015–0056.

Title: Individual Compliant of Employment Discrimination Form.

Form Numbers: DOT F 1050–8.

Type of Review: Renewal of previously approved form.

Abstract: The DOT will utilize the form to collect information necessary to process EEO discrimination complaints filed by employees, former employees, and applicants for employment with the Department. These complaints are processed in accordance with the U.S. Equal Employment Opportunity Commission's regulations, Title 29, Code of Federal Regulations, Part 1614, as amended. The DOT will use the form to: (a) Request requisite information from the applicant for processing his/her EEO discrimination complaint; and (b) obtain information to identify an individual or his or her attorney or other representative, if appropriate. An applicant's filing of an EEO discrimination complaint is solely voluntary. The DOT estimates that it takes an applicant approximately one hour to complete the form.

Respondents: Job applicants filing EEO discrimination complaints.

Estimated Number of Respondents: 10 per year.

Estimated Total Burden on Respondents: 10 hours per year.

Comments are invited on: (a) Whether the proposed collection of information is reasonable for the proper performance of the EEO functions of the Department, and (b) the accuracy of the Department's estimate of the burden of the proposed information collection. All responses to the notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Issued in Washington, DC, on September 8, 2016.

Leslie Proll,

Director, Departmental Office of Civil Rights.

[FR Doc. 2016–22190 Filed 9–15–16; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Privacy Act of 1974; Systems of Records

AGENCY: Department of the Treasury.

ACTION: Notice of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, 5 U.S.C. 552a the Department of the Treasury ("Treasury" or the "Department") proposes to update and reissue a current Department of the Treasury system of records titled, "Department of the Treasury.004—Freedom of Information Act/Privacy Act Request Records."

DATES: Submit comments on or before October 17, 2016. This new system will be effective October 17, 2016.

ADDRESSES: Comments should be sent to Ryan Law, Acting Deputy Assistant Secretary for Privacy, Transparency, and Records, Department of the Treasury, 1500 Pennsylvania Ave. NW., Washington, DC 20220. Attention: Revisions to Privacy Act Systems of Records.

Comments can be faxed to (202) 622–3895, or emailed to *privacy@treasury.gov.* For emails, please place "Revisions to SOR" in the subject line. Comments will be made available for public inspection upon written request. All comments received, including attachments and other supporting disclosure will be posted without change at *www.regulations.gov.* You should submit only information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: For general questions please contact: Ryan Law, Acting Deputy Assistant Secretary for Privacy, Transparency, and Records, Department of the Treasury, 1500 Pennsylvania Ave. NW., Washington, DC 20220, or at (202) 622–0790 (not toll-free).

SUPPLEMENTARY INFORMATION: In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of the Treasury proposes to update and reissue a current Treasury system of records titled, "Department of the Treasury.004—Freedom of Information Act/Privacy Act Request Records." Treasury.004 has been updated to include the Internal Revenue Service (IRS), to facilitate the disclosure of non-tax information to The Office of Government Information Services (OGIS) within the National Archives and Records Administration in accordance with routine use, "(10) To the National Archives and Records Administration, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(b), to review administrative agency policies, procedures and compliance with the Freedom of Information Act (FOIA), and to facilitate OGIS' offering of mediation services to resolve disputes between making FOIA requests and administrative agencies."

OGIS serves as a mediator between the various federal agencies that administer the FOIA and the requester. In that capacity, OGIS may come to the IRS to discuss specifics of a request and accordingly that discussion will involve access to the specific non-tax records. Adding IRS to the list of system managers authorizes IRS a discretionary authority to disclose to OGIS purely non-tax, Privacy Act protected information about FOIA requests. It will not authorize disclosure of any tax return or return information. Therefore, OGIS must obtain valid IRC 6103(c) disclosure consent from FOIA requesters before IRS can disclose to OGIS any returns or return information pertaining to any FOIA request.

Below is the description of the Treasury.004—Freedom of Information Act/Privacy Act Request Records." In accordance with 5 U.S.C. 552a(r), Treasury has provided a report of this system of records to the Office of Management and Budget and to Congress.

Ryan Law,

Acting Deputy Assistant Secretary for Privacy, Transparency, and Records.

TREASURY.004

SYSTEM NAME:

Freedom of Information Act/Privacy Act Request Records—Treasury.

SYSTEM LOCATION:

Department of the Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20220. The locations at which the system is maintained by Treasury components and their associated field offices are:

(1) Departmental Offices (DO), which includes the Office of Inspector General (OIG), the Community Development Financial Institutions Fund (CDFI), and Special Inspector General for the Troubled Asset Relief Program (SIGTARP);

(2) Alcohol and Tobacco Tax and Trade Bureau (TTB);

(3) Office of the Comptroller of the Currency (OCC);

(4) Bureau of Engraving and Printing (BEP);

(5) Fiscal Service (FS);

(6) United States Mint (MINT);

(7) Financial Crimes Enforcement Network (FinCEN);

(8) Treasury Inspector General for Tax Administration (TIGTA); and

(9) Internal Revenue Service (IRS).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have: (1) Requested access to records pursuant to the Freedom of Information Act, 5 U.S.C. 552 (FOIA), or who have appealed initial denials of their requests; and/or (2) made a request for access, amendment, or other action pursuant to the Privacy Act of 1974, 5 U.S.C. 552a (PA).

CATEGORIES OF RECORDS IN THE SYSTEM:

Requests for records or information pursuant to the FOIA/PA, which includes the names of individuals making written or electronically submitted requests for records under the FOIA/PA; the contact information of the requesting individual such as their mailing address, email address, and/or phone number; and the dates of such requests and their receipt. Supporting records include the written correspondence received from requesters and responses made to such requests; internal processing documents and memoranda; referrals and copies of records provided or withheld; and may include legal memoranda and opinions. Comparable records are maintained in this system with respect to any appeals made from initial denials of access, refusal to amend records, and lawsuits under the FOIA/PA.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Freedom of Information Act, 5 U.S.C. 552; Privacy Act of 1974, 5 U.S.C. 552a; and 5 U.S.C. 301.

PURPOSE(S):

The system is used by officials to administratively control and/or process requests for records to ensure compliance with the FOIA/PA and to collect data for the annual reporting requirements of the FOIA and other Departmental management report requirements. In addition, the system allows for online submission to expedite the consideration of requests.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records may be used to:

(1) Disclose pertinent information to appropriate Federal, foreign, State, local, tribal or other public authorities or self-regulatory organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where the disclosing agency becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation;

(2) Disclose information to a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations, in response to a court order, or in connection with criminal law proceedings;

(3) Provide information to a congressional office in response to an inquiry made at the request of the individual to whom the record pertains;

(4) Disclose information to another Federal agency to (a) permit a decision as to access, amendment or correction of records to be made in consultation with or by that agency, or (b) verify the identity of an individual or the accuracy of information submitted by an individual who has requested access to or amendment or correction of records;

(5) Disclose information to the Department of Justice when seeking legal advice, or when (a) the agency, or (b) any component thereof, or (c) any employee of the agency in his or her official capacity, or (d) any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee, or (e) the United States, where the agency determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice is deemed by the agency to be relevant and necessary to the litigation;

(6) Disclose information to the appropriate foreign, State, local, tribal, or other public authority or self-regulatory organization for the purpose of (a) consulting as to the propriety of access to or amendment or correction of information obtained from that authority or organization, or (b) verifying the identity of an individual who has requested access to or amendment or correction of records;

(7) Disclose information to contractors and other agents who have been engaged by the Department or one of its bureaus to provide products or services associated with the Department's or bureaus' responsibilities arising under the FOIA/PA;

(8) Disclose information to the National Archives and Records Administration for use in records management inspections;

(9) Disclose information to appropriate agencies, entities, and persons when (a) the Department suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (b) the Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Department or another agency or entity) that rely upon the compromised information; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

(10) To the National Archives and Records Administration, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(b), to review administrative agency policies, procedures and compliance with the Freedom of Information Act (FOIA), and to facilitate OGIS' offering of mediation services to resolve disputes between persons making FOIA requests and administrative agencies.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic media, computer paper printout, index file cards, and paper records in file folders.

RETRIEVABILITY:

Retrieved by name, subject, request file number, or other data element as may be permitted by an automated system.

SAFEGUARDS:

Protection and control of any sensitive but unclassified (SBU) records are in accordance with Treasury Directive Publication 71–10, Department of the Treasury Security Manual; DO P–910, Departmental Offices Information Technology Security Policy Handbook; Treasury Directive Publication 85–01, Treasury Information Technology Security Program; National Institute of Standards and Technology 800–122 and any supplemental guidance issued by individual bureaus; the National Institute of Standards and Technology Special Publication 800–53 Revision 3, Recommended Security Controls for Federal Information Systems and Organizations; and Guide to Protecting the Confidentiality of Personally

Identifiable Information. Access to the records is available only to employees responsible for the management of the system and/or employees of program offices who have a need for such information.

RETENTION AND DISPOSAL:

The records pertaining to FOIA/PA requests are retained and disposed of in accordance with the National Archives and Records Administration's General Record Schedule 14—Information Services Records.

SYSTEM MANAGER(S) AND ADDRESS:

Department of the Treasury: Official prescribing policies and practices—Departmental Disclosure Officer, Department of the Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20220.

The system managers for the Treasury components are:

(1) a. DO: Director, Disclosure Services, Department of the Treasury, Washington, DC 20220.

b. OIG: Director, Disclosure Services, Department of the Treasury, Washington, DC 20220.

c. CDFI: Director, Disclosure Services, Department of the Treasury, Washington, DC 20220.

d. SIGTARP: General Counsel, Office of the Special Inspector General for the Troubled Asset Relief Program, 1801 L Street NW., Washington, DC 20220.

(2) Alcohol and Tobacco Tax and Trade Bureau (TTB): 1310 G St. NW., Washington, DC 20220.

(3) BEP: Disclosure Officer, FOIA Office, 14th & C Streets SW., Washington, DC 20228.

(4) FS: Disclosure Officer, 401 14th Street SW., Washington, DC 20227.

(5) Mint: Disclosure Officer, 801 9th Street NW., 8th Floor, Washington, DC 20220.

(6) OCC: Disclosure Officer, Communications Division, 400 7th Street SW., Washington, DC 20024.

(7) FinCEN: P.O. Box 39, Vienna, VA 22183.

(8) TIGTA: Director, Human Capital and Support Services, 1401 H NW., Ste. 469, Washington, DC 20005.

(9) IRS: Internal Revenue Service Centralized Processing Unit—Stop 93A, Post Office Box 621506, Atlanta, GA 30362.

NOTIFICATION PROCEDURE:

Individuals seeking notification and access to any record contained in the system of records, or seeking to contest its content, may inquire in accordance with instructions pertaining to individual Treasury components appearing at 31 CFR part 1, subpart C, appendices A–M.

RECORD ACCESS PROCEDURES:

See "Notification procedure" above.

CONTESTING RECORD PROCEDURES:

See "Notification procedure" above.

RECORD SOURCE CATEGORIES:

The information contained in these files originates from individuals who make FOIA/PA requests and agency officials responding to those requests.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None. Please note that the Department has claimed one or more exemptions (see 31 CFR 1.36) for a number of its other systems of records under 5 U.S.C. 552a(j)(2) and (k)(1), (2), (3), (4), (5), and (6). During the course of a FOIA/PA action, exempt materials from those other systems may become a part of the case records in this system. To the extent that copies of exempt records from those other systems have been recompiled and/or entered into these FOIA/PA case records, the Department claims the same exemptions for the records as they have in the original primary systems of records of which they are a part.

[FR Doc. 2016–22069 Filed 9–15–16; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF VETERANS AFFAIRS

Corporate Senior Executive Management Office; Notice of Performance Review Board Members

AGENCY: Corporate Senior Executive Management Office, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Under the provisions of 5 U.S.C. 4314(c)(4) agencies are required to publish a notice in the **Federal Register** of the appointment of Performance Review Board (PRB) members. This notice announces the appointment of individuals to serve on the PRB of the Department of Veterans Affairs.

DATES: August 25, 2016.

ADDRESSES: Corporate Senior Executive Management Office, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420.

FOR FURTHER INFORMATION CONTACT: Contact Tia N. Butler, Executive Director, Corporate Senior Executive Management Office (052), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–7865.

SUPPLEMENTARY INFORMATION: The membership of the Department of Veterans Affairs Performance Review Board is as follows:

Snyder, Robert D. (Chair)
Wright, Vivieca (Simpson)
Breyfogle, Cynthia
McCarthy, Maureen Fay
Murray, Patricia
Mayes, Bradley
Frueh, Michael
Giddens, Gregory
Hanson, Anita
Hogan, Michael
Thompson, Ronald
Hudson, Kathy
Yehia, Baligh, R. (Alternate)
Pape, Lisa (Alternate)
Rawls, Cheryl (Alternate)
Reynolds, Robert (Alternate)
Sullivan, Matthew (Alternate)
Lowe, Roberta (Alternate)
Tran, Dat (Alternate)
Kennedy, Tammy (Alternate)
Enomoto, Kana (Alternate)
Constantian, Alan (Alternate)

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, approved this document for publication on August 25, 2016.

Authority: 5 U.S.C. 4314(c)(4).

Dated: August 25 2016.

Jeffrey Martin,

Office Program Manager, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2016–22298 Filed 9–15–16; 8:45 am]

BILLING CODE 8320–01–P

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Vol. 81 Friday,
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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 416, 418, et al.

Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 416, 418, 441, 460, 482, 483, 484, 485, 486, 491, and 494

[CMS–3178–F]

RIN 0938–AO91

Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers to plan adequately for both natural and man-made disasters, and coordinate with federal, state, tribal, regional, and local emergency preparedness systems. It will also assist providers and suppliers to adequately prepare to meet the needs of patients, residents, clients, and participants during disasters and emergency situations. Despite some variations, our regulations will provide consistent emergency preparedness requirements, enhance patient safety during emergencies for persons served by Medicare- and Medicaid-participating facilities, and establish a more coordinated and defined response to natural and man-made disasters.

DATES: *Effective date:* These regulations are effective on November 15, 2016.

Incorporation by reference: The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register November 15, 2016.

Implementation date: These regulations must be implemented by November 15, 2017.

FOR FURTHER INFORMATION CONTACT:
Janice Graham, (410) 786–8020.
Mary Collins, (410) 786–3189.
Diane Corning, (410) 786–8486.
Kianna Banks (410) 786–3498.
Ronisha Blackstone, (410) 786–6882.
Alpha-Banu Huq, (410) 786–8687.
Lisa Parker, (410) 786–4665.

SUPPLEMENTARY INFORMATION:

Acronyms

AAAHC Accreditation Association for Ambulatory Health Care, Inc.
AAAASF American Association for Accreditation for Ambulatory Surgery Facilities, Inc.
AAR/IP After Action Report/Improvement Plan
ACHC Accreditation Commission for Health Care, Inc.
ACHE American College of Healthcare Executives
AHA American Hospital Association
AO Accrediting Organization
AOA/HFAP American Osteopathic Association/Healthcare Facilities Accreditation Program
ASC Ambulatory Surgical Center
ARCAH Accreditation Requirements for Critical Access Hospitals
ASPR Assistant Secretary for Preparedness and Response
BLS Bureau of Labor Statistics
BTCDP Bioterrorism Training and Curriculum Development Program
CAH Critical Access Hospital
CAMCAH Comprehensive Accreditation Manual for Critical Access Hospitals
CAMH Comprehensive Accreditation Manual for Hospitals
CASPER Certification and the Survey Provider Enhanced Reporting
CDC Centers for Disease Control and Prevention
CON Certificate of Need
CfCs Conditions for Coverage and Conditions for Certification
CHAP Community Health Accreditation Program
CMHC Community Mental Health Center
CMS Centers for Medicare and Medicaid Services
COI Collection of Information
CoPs Conditions of Participation
CORF Comprehensive Outpatient Rehabilitation Facilities
CPHP Centers for Public Health Preparedness
CRI Cities Readiness Initiative
DHS Department of Homeland Security
DHHS Department of Health and Human Services
DNV GL Det Norske Veritas GL—Healthcare
DOL Department of Labor
DPU Distinct Part Units
DSA Donation Service Area
EOP Emergency Operations Plans
EC Environment of Care
EMP Emergency Management Plan
EP Emergency Preparedness
ESAR–VHP Emergency System for Advance Registration of Volunteer Health Professionals
ESF Emergency Support Function
ESRD End-Stage Renal Disease
FEMA Federal Emergency Management Agency
FDA Food and Drug Administration
FORHP Federal Office of Rural Health Policy
FRI Federal Reserve Inventories
FQHC Federally Qualified Health Center
GAO Government Accountability Office
HFAP Healthcare Facilities Accreditation Program
HHA Home Health Agencies
HPP Hospital Preparedness Program
HRSA Health Resources and Services Administration
HSC Homeland Security Council
HSEEP Homeland Security Exercise and Evaluation Program
HSPD Homeland Security Presidential Directive
HVA Hazard Vulnerability Analysis or Assessment
ICFs/IID Intermediate Care Facilities for Individuals with Intellectual Disabilities
ICR Information Collection Requirements
IDG Interdisciplinary Group
IOM Institute of Medicine
JPATS Joint Patient Assessment and Tracking System
LEP Limited English Proficiency
LD Leadership
LPHA Local Public Health Agencies
LSC Life Safety Code
LTC Long Term Care
MMRS Metropolitan Medical Response System
MRC Medical Reserve Corps
MS Medical Staff
NDMS National Disaster Medical System
NFs Nursing Facilities
NFPA National Fire Protection Association
NIMS National Incident Management System
NIOSH National Institute for Occupational Safety and Health
NLTN National Laboratory Training Network
NRP National Response Plan
NRF National Response Framework
NSS National Security Staff
OBRA Omnibus Budget Reconciliation Act
OIG Office of the Inspector General
OPHPR Office of Public Health Preparedness and Response
OPO Organ Procurement Organization
OPT Outpatient Physical Therapy
OPTN Organ Procurement and Transplantation Network
OSHA Occupational Safety and Health Administration
PACE Program for the All-Inclusive Care for the Elderly
PAHPA Pandemic and All-Hazards Preparedness Act
PAHPRA Pandemic and All-Hazards Preparedness Reauthorization Act
PCT Patient Care Technician
PPE Personal Protection Equipment
PHEP Public Health Emergency Preparedness
PHS Act Public Health Service Act
PIN Policy Information Notice
PPD Presidential Policy Directive
PRTF Psychiatric Residential Treatment Facilities
QAPI Quality Assessment and Performance Improvement
QIES Quality Improvement and Evaluation System
RFA Regulatory Flexibility Act
RNHCIs Religious Nonmedical Health Care Institutions
RHC Rural Health Clinic
SAMHSA Substance Abuse and Mental Health Services Administration
SLP Speech Language Pathology
SNF Skilled Nursing Facility
SNS Strategic National Stockpile
TEFRA Tax Equity and Fiscal Responsibility Act
TFAH Trust for America's Health
TJC The Joint Commission
TRACIE Technical Resources, Assistance Center, and Information Exchange

TTX Tabletop Exercise
UMRA Unfunded Mandates Reform Act
UNOS United Network for Organ Sharing
UPMC University of Pittsburgh Medical Center
WHO World Health Organization

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  - P. Emergency Preparedness Regulations for Community Mental Health Centers (CMHCs) (§ 485.920)
  - Q. Emergency Preparedness Regulations for Organ Procurement Organizations (OPOs) (§ 486.360)
  - R. Emergency Preparedness Regulations for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (§ 491.12)
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I. Overview

A. Executive Summary

1. Purpose

We have reviewed existing Medicare emergency regulatory preparedness requirements for both providers and suppliers. We found that many providers and suppliers have emergency preparedness requirements, but those requirements do not go far enough in ensuring that these providers and suppliers are equipped and prepared to help protect those they serve during emergencies and disasters. Hospitals, for example, are currently required to have emergency power and lighting in some specified areas and there must be facilities for emergency gas and water supply. We believe that these existing requirements are generally insufficient in the face of the needs of the patients, staff and communities, and do not address inconsistency in the level of emergency preparedness amongst healthcare providers. For example, while some accreditation organizations have standards that exceed CMS' current requirements for hospitals by requiring them to conduct a risk assessment, there are other providers and suppliers who do not have any emergency preparedness requirements, such as Community Mental Health Centers (CMHCs) and Psychiatric Residential Treatment Facilities (PRTFs). We concluded that current emergency preparedness requirements are not comprehensive enough to address the complexities of the actual emergencies. Over the past several years, the United States has been challenged by several natural and man-made disasters. As a result of the September 11, 2001 terrorist attacks, the subsequent anthrax attacks, the catastrophic hurricanes in the Gulf Coast states in 2005, flooding in the Midwestern states in 2008, the 2009 H1N1 influenza pandemic, tornadoes and floods in the spring of 2011, and Hurricane Sandy in 2012, our nation's health security and readiness for public health emergencies have been on the national agenda. This final rule issues emergency preparedness requirements that establish a comprehensive, consistent, flexible, and dynamic regulatory approach to emergency preparedness and response that incorporates the lessons learned from the past, combined with the proven best practices of the present. We recognize that central to this approach is to develop and guide emergency preparedness and response within the framework of our national healthcare system. To this end, these requirements also encourage providers and suppliers to coordinate their preparedness efforts within their own communities and states as well as across state lines, as necessary, to achieve their goals.

2. Summary of the Major Provisions

We are issuing emergency preparedness requirements that will be consistent and enforceable for all affected Medicare and Medicaid providers and suppliers (referred to collectively as "facilities," throughout the remainder of this final rule where applicable). This final rule addresses the three key essentials we believe are necessary for maintaining access to healthcare services during emergencies: safeguarding human resources, maintaining business continuity, and protecting physical resources. Current regulations for Medicare and Medicaid providers and suppliers do not adequately address these key elements.

Based on our research and consultation with stakeholders, we have identified four core elements that are central to an effective and comprehensive framework of emergency preparedness requirements for the various Medicare- and Medicaid-participating providers and suppliers. The four elements of the emergency preparedness program are as follows:

- *Risk assessment and emergency planning:* We are requiring facilities to perform a risk assessment that uses an "all-hazards" approach prior to establishing an emergency plan. The all-hazards risk assessment will be used to identify the essential components to be integrated into the facility emergency plan. An all-hazards approach is an integrated approach to emergency preparedness planning that focuses on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters. This approach is specific to the location of the provider or supplier and considers the particular types of hazards most likely to occur in their areas. These may include, but are not limited to, care-related emergencies; equipment and power failures; interruptions in communications, including cyber-attacks; loss of a portion or all of a facility; and, interruptions in the normal supply of essentials, such as water and food. Additional information on the emergency preparedness cycle can be found at the Federal Emergency Management Agency (FEMA) National Preparedness System Web site located at: *https://www.fema.gov/threat-and-hazard-identification-and-risk-assessment.*

- *Policies and procedures:* We are requiring that facilities develop and implement policies and procedures that support the successful execution of the emergency plan and risks identified during the risk assessment process.
- *Communication plan:* We are requiring facilities to develop and maintain an emergency preparedness communication plan that complies with both federal and state law. Patient care must be well-coordinated within the facility, across healthcare providers, and with state and local public health departments and emergency management agencies and systems to protect patient health and safety in the event of a disaster. The following link is to FEMA's comprehensive preparedness guide to develop and maintain emergency operations plans: *https://www.fema.gov/media-library-data/20130726-1828-25045-0014/cpg_101_comprehensive_preparedness_guide_developing_and_maintaining_emergency_operations_plans_2010.pdf.* During an emergency, it is critical that hospitals, and all providers/suppliers, have a system to contact appropriate staff, patients' treating physicians, and other necessary persons in a timely manner to ensure continuation of patient care functions throughout the facilities and to ensure that these functions are carried out in a safe and effective manner.
- *Training and testing:* We are requiring that a facility develop and maintain an emergency preparedness training and testing program. A well-organized, effective training program must include initial training for new and existing staff in emergency preparedness policies and procedures as well as annual refresher trainings. The facility must offer annual emergency preparedness training so that staff can demonstrate knowledge of emergency procedures. The facility must also conduct drills and exercises to test the emergency plan to identify gaps and areas for improvement. The Homeland Security Exercise and Evaluation Program (HSEEP), developed by FEMA, includes a section on the establishment of a Training and Exercise Planning Workshop (TEPW). The TEPW section provides guidance to organizations in conducting an annual TEPW and developing a Multi-year Training and Exercise Plan (TEP) in line with the (HSEEP): *http://www.fema.gov/media-library-data/20130726-1914-25045-8890/hseep_apr13_.pdf.*

B. Current State of Emergency Preparedness

As previously discussed, numerous natural and man-made disasters have challenged the United States over the past several years. Disasters can disrupt the environment of healthcare and change the demand for healthcare services; therefore, it is essential that healthcare facilities integrate emergency management into their daily functions and values. On December 27, 2013, we published a proposed rule titled, "Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers" (78 FR 79082). In this proposed rule we included a robust discussion about the current state of emergency preparedness and federal emergency preparedness activities that have established a foundation for the development and expansion of healthcare emergency preparedness systems. In addition, the December 2013 proposed rule included an appendix of the numerous resources and documents used to develop the proposed rule. We refer readers to the proposed rule for this background information.

The December 2013 proposed rule included discussion of previous events, such as the 2009 H1N1 influenza pandemic, the 2001 anthrax attacks, the tornados in 2011 and 2012, and Hurricane Sandy in 2012. In 2014, the United States faced a number of new and emerging diseases, such as MERS-CoV and Ebola, and a nationwide outbreak of Enterovirus D68, which was confirmed in 938 people in 46 states between mid-August and October 21, 2014 (*http://www.cdc.gov/non-polio-enterovirus/outbreaks/EV-D68-outbreaks.html*). We believe that finalizing the emergency preparedness rule is an important part of improving the national response to Ebola and any infectious disease threats. Healthcare providers have raised concerns about their safety when caring for patients with Ebola, citing the need for advanced preparation, effective policies and procedures, communication plans, and sufficient training and testing, particularly for personal protection equipment (PPE). The response highlighted the importance of establishing written procedures, protocols, and policies ahead of an emergency event. With the finalization of the emergency preparedness rule, this type of planning will be mandated for Medicare and Medicaid participating hospitals and other providers and suppliers through the conditions of participation (CoPs) and conditions for coverage (CfCs) established by this rule.

C. Statutory and Regulatory Background

Various sections of the Social Security Act (the Act) define the types of providers and suppliers that may participate in Medicare and Medicaid and list the requirements that each provider and supplier must meet to be eligible for Medicare and Medicaid participation. The Act also authorizes the Secretary to establish other requirements as necessary to protect the health and safety of patients, although the wording of such authority differs slightly between provider and supplier types. Such requirements may include the CoPs for providers, CfCs for suppliers, and requirements for long-term care facilities. The CoPs and CfCs are intended to protect public health and safety and promote high quality care for all persons. Furthermore, the Public Health Service (PHS) Act sets forth additional regulatory requirements that certain Medicare providers and suppliers are required to meet in order to participate.

The following are the statutory and regulatory citations for the providers and suppliers for which we are issuing emergency preparedness regulations:

- Religious Nonmedical Health Care Institutions (RNHCIs)—section 1821 of the Act and 42 CFR 403.700 through 403.756.
- Ambulatory Surgical Centers (ASCs)—section 1832(a)(2)(F)(i) of the Act and 42 CFR 416.2 and 416.40 through 416.52.
- Hospices—section 1861(dd)(1) of the Act and 42 CFR 418.52 through 418.116.
- Inpatient Psychiatric Services for Individuals Under Age 21 in Psychiatric Residential Treatment Facilities (PRTFs)—sections1905(a) and 1905(h) of the Act and 42 CFR 441.150 through 441.182 and 42 CFR 483.350 through 483.376.
- Programs of All-Inclusive Care for the Elderly (PACE)—sections 1894, 1905(a), and 1934 of the Act and 42 CFR 460.2 through 460.210.
- Hospitals—section 1861(e)(9) of the Act and 42 CFR 482.1 through 482.66.
- Transplant Centers—sections 1861(e)(9) and 1881(b)(1) of the Act and 42 CFR 482.68 through 482.104.
- Long Term Care (LTC) Facilities—Skilled Nursing Facilities (SNFs)—under section 1819 of the Act, Nursing Facilities (NFs)—under section 1919 of the Act, and 42 CFR 483.1 through 483.180.

- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)—section 1905(d) of the Act and 42 CFR 483.400 through 483.480.
- Home Health Agencies (HHAs)—sections 1861(o), 1891 of the Act and 42 CFR 484.1 through 484.55.
- Comprehensive Outpatient Rehabilitation Facilities (CORFs)—section 1861(cc)(2) of the Act and 42 CFR 485.50 through 485.74.
- Critical Access Hospitals (CAHs)—sections 1820 and 1861(mm) of the Act and 42 CFR 485.601 through 485.647.
- Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services—section 1861(p) of the Act and 42 CFR 485.701 through 485.729.
- Community Mental Health Centers (CMHCs)—section 1861(ff)(3)(B)(i)(ii) of the Act, section 1913(c)(1) of the PHS Act, and 42 CFR 410.110.
- Organ Procurement Organizations (OPOs)—section 1138 of the Act and section 371 of the PHS Act and 42 CFR 486.301 through 486.348.
- Rural Health Clinics (RHCs)—section 1861(aa) of the Act and 42 CFR 491.1 through 491.11; Federally Qualified Health Centers (FQHCs)—section 1861(aa) of the Act and 42 CFR 491.1 through 491.11, except 491.3.
- End-Stage Renal Disease (ESRD) Facilities—sections 1881(b), 1881(c), 1881(f)(7) of the Act and 42 CFR 494.1 through 494.180.

The proposed rule responded to concerns from the Congress, the healthcare community, and the public regarding the ability of healthcare facilities to plan and execute appropriate emergency response procedures for disasters. In the proposed rule, we identified four core elements that we believe are central to an effective emergency preparedness system and must be addressed to offer a more comprehensive framework of emergency preparedness requirements for the various Medicare- and Medicaid-participating providers and suppliers. The four elements are—(1) risk assessment and emergency planning; (2) policies and procedures; (3) communication plan; and (4) training and testing. We proposed that these core components be used across provider and supplier types as diverse as hospitals, organ procurement organizations, and home health agencies, while attempting to tailor requirements for individual provider and supplier types to meet their specific needs and circumstances, as well as the needs of their patients, residents, clients, and participants. These proposals are refined and adopted in this final rule.

II. Provisions of the Proposed Rule and Responses to Public Comments

In response to our December 2013 proposed rule, we received nearly 400 public comments. Commenters included individuals, healthcare professionals and corporations, national associations, health departments and emergency management professionals, and individual facilities that would be impacted by the regulation. Most comments centered around the hospital requirements, but could be applied to the additional provider and supplier types. We also received comments specific to the requirements we proposed for other individual provider and supplier types. In addition, we solicited comments on specific issues. We have organized our responses to the comments as follows: (1) General comments; (2) implementation date; (3) comments specific to hospitals and those that apply to the overall requirements of the regulation; and (4) comments specific to other providers and suppliers.

A. General Comments

We received the following comments suggesting improvement to our regulatory approach or requesting clarification of the resources used to develop our proposals:

Comment: Most commenters supported our proposal to require Medicare and Medicaid participating facilities to establish an emergency preparedness plan. Many of these commenters noted that this proposal is timely and necessary in light of past emergencies and natural disasters.

Response: We thank the commenters for their support. We continue to believe that our current regulations for Medicare and Medicaid providers and suppliers do not adequately address emergency preparedness planning and that emergency preparedness CoPs for providers and CfCs for suppliers should be implemented at this time.

Comment: Several commenters disagreed with our proposal to establish emergency preparedness requirements for Medicare and Medicaid providers and suppliers. Some commenters were concerned that this proposal would place undue burden and financial strain on facilities. Most of these commenters stated that it would be difficult to implement additional regulations without additional payment through Medicare, Medicaid, or the Hospital Preparedness Program (HPP). The commenters also stated that facilities would need more time to comply with the proposed requirements.

A few commenters disagreed with our statement that hospitals should have emergency preparedness plans and stated that hospitals are already prepared for emergencies. A commenter objected to the statement that hospital leadership has not prioritized disaster preparedness.

A commenter recommended that the proposed emergency preparedness requirements be reduced and simplified to reflect the minimum requirements that each provider type is expected to meet. Other commenters objected to the entire proposal and the establishment of additional regulations for healthcare facilities.

Response: We disagree with the commenters who stated that the emergency preparedness regulations are inappropriate or unnecessary. Healthcare facilities in the United States have faced many challenges over the years including hurricanes, tornados, floods, wild fires, and pandemics. Facilities that do not have plans established prior to an emergency or a disaster may face difficulties providing continuity of care for their patients. In addition, without proper training, healthcare workers may find it difficult to implement emergency preparedness plans during an emergency or a disaster.

Upon review of the current emergency preparedness requirements for providers and suppliers participating in Medicare and Medicaid, we concluded that the current requirements are not comprehensive enough to address the complexities of actual emergencies. We believe that, currently, in the event of a disaster, healthcare facilities across the nation will not have the necessary emergency planning and preparation in place to adequately protect the health and safety of their patients. In addition, we believe that the current regulatory patchwork of federal, state, and local laws and guidelines, combined with various accrediting organizations' emergency preparedness standards, falls far short of what is needed for healthcare facilities to be adequately prepared for a disaster. Therefore, we proposed to establish comprehensive, consistent, and flexible emergency preparedness regulations that incorporate lessons learned from the past with the proven best practices of the present. Finalizing these proposals, with the modifications discussed later in this final rule, will help healthcare facilities be better prepared in case of a disaster or emergency. We note that the majority of the comments to the proposed rule agree with the establishment of some type of regulatory framework for emergency preparedness planning, which further supports our position that establishing emergency preparedness regulations is the most appropriate course of action.

In response to comments that request additional time for compliance or additional funds, we refer readers to the discussion on the implementation date and further discussions on funding in this final rule.

Comment: Some commenters stated that the term "ensure" was used numerous times in the proposed rule and that the term was over-used. Commenters stated that in some circumstances we stated providers and suppliers had to "ensure" elements of the plan that might be beyond their control during an emergency. A commenter suggested that we replace the word "ensure" with the term "strive to achieve."

Response: We used the word "ensure" or "ensuring" to convey that each provider and supplier will be held accountable for complying with the requirements in this rule. However, to avoid any ambiguity, we have removed the term "ensure" and "ensuring" from the regulation text of all providers and suppliers and have addressed the requirements in a more direct manner.

Comment: Some commenters were concerned that the proposed emergency preparedness requirements duplicate existing requirements by The Joint Commission (TJC). TJC is a CMS-approved accrediting organization that has standards and survey procedures that meet or exceed those used by CMS and state surveyors. Facilities accredited under a Medicare approved accreditation program, such as TJC's, may be "deemed" by CMS to be in compliance with the CoPs. Most of these commenters recommended that CMS rely on existing TJC standards. Other commenters noted that CMS used TJC manual citations from 2007 through 2008. The commenters noted that changes have been made since then and recommended that CMS refer to the most recent TJC manual.

Response: We discussed TJC standards in the proposed rule as a point of reference for emergency preparedness standards that currently exist for healthcare facilities, absent additional federal regulations. We note that CMS has the authority to create and modify CoPs, which establish the requirements a provider must meet to participate in the Medicare or Medicaid program. Also, we note that facilities that exceed CMS's requirements will still remain compliant.

Comment: A few commenters stated that the proposal did not take into account the differences that exist between individual facilities. The commenters noted that the proposal does not acknowledge the diversity of different facilities and instead requires a "one size fits all" emergency preparedness plan. The commenters recommended that CMS address the variation between facilities in the emergency preparedness requirements.

Some commenters stated that the proposed requirements are inappropriate because they mostly apply to hospitals, and cannot be applied to other healthcare settings. A commenter noted that smaller hospitals with limited capabilities, like LTCHs, should be allowed to work with their local emergency response networks to develop emergency preparedness plans that reflect those hospitals' limitations.

Response: We believe our approach, with the changes to our proposal discussed later in this final rule, appropriately addresses the differences between the 17 provider and supplier types covered by these regulations. We believe that emergency preparedness regulations that are too specific may become outdated over time, as technology and the nature of threats change, and that emergency preparedness regulations that are too broad may be ineffective. Therefore, we proposed four main components that are consistent with the principles as set forth in the National Preparedness Cycle contained within the National Preparedness System (link (see: *https://www.fema.gov/national-preparedness-system*) that can be used across diverse healthcare settings, while tailoring specific requirements for individual provider and supplier types based on their needs and circumstances, as well as the needs and circumstances of their patients, residents, clients, and participants. We continue to believe that these four components, and the variations in the specific requirements of these components, appropriately address variation amongst provider and supplier settings and facilities with an appropriate amount of flexibility. We do not believe that we have taken a "one size fits all" approach in these regulations.

We agree with the commenter who stated that smaller hospitals should be allowed to work with their local health department and emergency management agency to develop emergency preparedness plans and we encourage these facilities to engage in healthcare coalitions in their area for assistance in meeting these requirements. However, we note that we are not mandating that smaller facilities confer with local emergency response networks while developing their emergency preparedness plans.

Comment: A few commenters stated that the proposed provisions were too specific and detailed. Some commenters believed that, like other CoPs, the proposal should include provisions that are more flexible. The commenters noted that more specificity should be included in CMS' interpretive guidance documents (IGs).

Response: We disagree with commenters. We believe that these regulations strike a balance between the specific and the general. We have not prescribed or mandated specific technology or tools, nor have we included detailed requirements for how emergency preparedness plans should be written. The regulations are broad enough that facilities can formulate an effective emergency preparedness plan, based on a facility-based and community-based risk assessment utilizing an all-hazards approach, that includes appropriate policies and procedures, a communication plan, and training and testing. In meeting the emergency preparedness requirements, providers can tailor specific details to their facilities' and their patients' needs. Facilities can also exceed the requirements in this final rule, if they believe it is in their patients' and their facilities' interests to do so.

Comment: A few commenters suggested that CMS require facilities to include other entities, stakeholders, and individuals in their emergency preparedness planning. Specifically, a few commenters suggested that facilities include patients, their family members, and vulnerable populations, including older adults, people with disabilities, and those who are linguistically isolated, in their emergency preparedness planning. A few commenters also recommended that facilities include patients and their families in emergency preparedness education. A few commenters recommended that front line workers and their workers' unions be included in the emergency preparedness planning. A commenter suggested that CMS emphasize the full continuum of emergency management activities and identify relevant national associations and resources for each provider type.

A commenter noted that local emergency management officials are rarely included in emergency planning. The commenter recommended adding a requirement that would require facilities to submit their emergency preparedness plan to their local emergency management agency for review and assessment, and for assistance on sheltering and evacuation procedures.

Response: In the proposed rule, we proposed to require certain facilities to develop a method for sharing information from the emergency plan that the facility determines is appropriate with patients/residents and their families or representatives. A facility may choose to involve other entities in the development of an emergency preparedness plan or they can provide emergency preparedness education to patients' families and caregivers. During the development of the emergency plan, facilities may also choose to include patients, community members and others in the process. However, we are not mandating these actions as we believe such a requirement would impose an excessive burden on providers and suppliers; instead, we encourage and will allow facilities the discretion to confer with entities and resources that they consider appropriate while creating an emergency preparedness plan and strongly encourage that facilities include individuals with disabilities and others with access and functional needs in their planning.

Comment: A commenter recommended that emergency preparedness plans should account for children's special needs during an emergency. The commenter stated that emergency preparedness plans should include children's medication and medical device needs, challenges regarding patient transfer for neonatal and pediatric intensive care patients, and issues involving behavioral health and family reunification.

A commenter recommended that CMS collaborate closely with the Emergency Medical Services for Children (EMSC) program administered by the Health Resources and Services Administration (HRSA). The commenter noted that this program focuses on improving the pediatric components of the EMS system.

Response: We appreciate the commenter's concerns. As required in § 482.15(a)(1), (2), and (3), when a provider or supplier develops an emergency preparedness plan, we will expect that the provider/supplier will use a facility-based and community-based risk assessment to develop a plan that addresses that facility's patient population, including at-risk populations. If the provider serves children, or if the majority of its patient population is children, as is the case for children's hospitals, we will expect the provider to take into account children's access and functional needs during an emergency or disaster in its emergency preparedness plan.

Comment: A few commenters questioned CMS' definition of an emergency. A commenter disagreed with the proposed rule's definition of "emergency" and "disaster." The commenter stated that the proposed rule definitions exclude internal or smaller disasters that a hospital may declare. Furthermore, the commenter noted that the definitions should include mass casualty incidents and internal emergencies or disasters that a facility may declare. Another commenter requested clarification as to whether the regulation applies to external or internal emergencies.

Response: In the proposed rule, we defined an "emergency" or "disaster" as an event affecting the overall target population or the community at large that precipitates the declaration of a state of emergency at a local, state, regional, or national level by an authorized public official such as a Governor, the Secretary of the Department of Health and Human Services (HHS), or the President of the United States. However, we agree with the commenter's observation that the definition of an "emergency" or "disaster" should include internal emergency or disaster events. Therefore, we clarify our statement that an "emergency" or "disaster" is an event that can affect the facility internally as well as the overall target population or the community at large.

We believe that hospitals should have a single emergency plan that addresses all-hazards, including internal emergencies and a man-made emergency (or both) or natural disaster. Hospitals have the discretion to determine when to activate their emergency plan and whether to apply their emergency plan to internal or smaller emergencies or disasters that may occur within their facilities. We encourage hospitals to prepare for all-hazards that may affect their patient population and apply their emergency preparedness plans to any emergency or disaster that may arise. Furthermore, we encourage hospitals that may be dealing with an internal emergency or disaster to maintain communication with external emergency preparedness entities and other facilities where appropriate.

Comment: A few commenters were concerned that the proposed rule did not require planning for recovery of operations. The commenters recommended that CMS include requirements for facilities to plan for the return of normal operations after an emergency. A commenter recommended that CMS include requirements for provider preparedness in case of an information technology (IT) system failure.

Response: We understand the commenter's concerns and believe that facilities should consider planning for recovery of operations during the emergency or disaster response. Recovery of operations will require that facilities coordinate efforts with the relevant health department and emergency management agencies to restore facilities to their previous state prior to the emergency or disaster event. Our new emergency preparedness requirements focus on continuity of operations, not recovery of operations. Facilities can choose to include recovery of operations planning in their emergency preparedness plan, but we have not made recovery of operations planning a requirement.

We refer commenters that are interested in recovery of operations planning to the following resources for more information:

- National Disaster Recovery Framework (NDRF): *https://www.fema.gov/national-disaster-recovery-framework.*
- Continuity Guidance Circular 1 (CGC 1), and Continuity Guidance for Non-Federal Entities (States, Territories, Tribal, and Local Government Jurisdictions and Private Sector Organizations) *http://www.fema.gov/pdf/about/org/ncp/cont_guidance1.pdf.*
- National Preparedness System (*https://www.fema.gov/national-preparedness-system*)
- Comprehensive Preparedness Guide 101 *http://www.fema.gov/media-library-data/20130726-1828-25045-0014/cpg_101_comprehensive_preparedness_guide_developing_and_maintaining_emergency_operations_plans_2010.pdf*)

Comment: A commenter requested clarification on whether hospitals would have direct access to the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR–VHP).

A commenter recommended that CMS work with other federal agencies, including the Department of Homeland Security (DHS) and the Federal Emergency Management Agency (FEMA) to expand ESAR–VHP and Medical Reserve Corps (MRC) team deployments to a 3 month rotation basis. The commenter also recommended that CMS purchase and pre-position Federal Reserve Inventories (FRI) at healthcare distributorships.

Response: Hospitals do not have direct access to the Emergency System for Advance Registration of Volunteer Health Professional (ESAR–VHP). The Assistant Secretary for Preparedness and Response (ASPR) manages the ESAR–VHP program. The program is administered on the state level. A hospital would request volunteer health professionals through State Emergency Management. For more information, reviewers may email ASPR at *esarvhp@hhs.gov* or visit the ESAR/VHP Web site: *http://www.phe.gov/esarvhp/pages/home.aspx.* Volunteer deployments typically last for 2 weeks and are not extended without the agreement of the volunteer.

In regards to the comment on the Federal Reserve Inventories, we believe that the commenter may be referring to the Strategic National Stockpile (SNS). The SNS program is a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, and medical supplies. It is not within CMS' purview to purchase, administer, or maintain SNS stock. We refer commenters who have questions about the SNS program to the Centers for Disease Control and Prevention (CDC) Web site at *http://emergency.cdc.gov/stockpile/index.asp.*

Comment: A commenter noted that CMS did not include emergency preparedness requirements for transport units (fire and rescue units, and ambulances). Furthermore, the commenter questioned whether a Certificate of Need (CON) is necessary during an emergency.

Another commenter questioned why large single specialty and multispecialty medical groups are not discussed as included or excluded in this rule. The commenter noted that these entities have Medicare and Medicaid provider status; therefore, should be included in this rule. Another commenter questioned whether the proposed regulations would apply to residential drug and alcohol treatment centers. The commenter noted that if this is the case, it would be difficult for these centers to meet the proposed requirements due to lack of funding.

Response: The emergency preparedness requirements only pertain to the 17 provider and supplier types discussed previously in this rule, which have existing CoPs or CfCs. These provider and supplier types do not include fire and rescue units, and ambulances, or single-specialty/multi-specialty medical groups. Entities that work with hospitals or any of the other provider and supplier types covered by this regulation may have a role in the provider's or supplier's emergency preparedness plan, and providers or suppliers may choose to consider the role of these entities in their emergency preparedness plan. In addition, we note that CMS does not exercise regulatory authority over drug and alcohol treatment centers.

In response to the question about a Certificate of Need, we note that facilities must formulate an emergency preparedness plan that complies with state and local laws. A Certificate of Need is a document that is needed in some states and local jurisdiction before the creation, acquisition, or expansion of a facility is allowed. Facilities should check with their state and local authorities in regards to Certificate of Need requirements.

Comment: A commenter requested clarification on a facility's responsibility to patients that have already evacuated the facility on their own.

Response: Facilities are required to track the location of staff and patients in the facility's care during an emergency. The facility is not required to track the location of patients who have voluntarily left on their own, since they are no longer in the facility's care. However, if a patient voluntarily leaves a facility's care during an emergency or a disaster, the facility may choose to inform the appropriate health department and emergency management or emergency medical services authorities if it believes the patient may be in danger.

Comment: A commenter questioned whether the requirements take into account the role of the physician during emergency preparedness planning. The commenter questioned whether physicians will be required to provide feedback during the planning process, whether physicians would have a role in preserving patient medical documentation, whether physicians would be involved in determining arrangements for patients during a cessation of operations, and to what extent physicians would be required to participate in training and testing.

Response: Individual physicians are not required, but are encouraged, to develop and maintain emergency preparedness plans. However, physicians that work in a facility that is required to develop and maintain an emergency preparedness plan can and are encouraged to provide feedback or suggestions for best practices. In addition, physicians that are employed by the facility and all new and existing staff must participate in emergency preparedness training and testing. We have not mandated a specific role for physicians during an emergency or disaster event, but we expect facilities to delineate responsibilities for all of their facility's workers in their emergency preparedness plans and to determine the appropriate level of training for each professional role.

Comment: A commenter objected to use of the term "volunteers" in the proposed rule. The commenter stated that this term was not defined and recommended that the proposal be limited to healthcare professionals used to address surge needs during an emergency. Another commenter recommended that the regulation text should be revised to include the language, "Use of health care volunteers", to further clarify this distinction.

Response: We provided information on the use of volunteers in the proposed rule (78 FR 79097), specifically with reference to the Medical Reserve Corps and the ESAR–VHP programs. Private citizens or medical professionals not employed by a hospital or facility often offer their voluntary services to hospitals or other entities during an emergency or disaster event. Therefore, we believe that facilities should have policies and procedures in place to address the use of volunteers in an emergency, among other emergency staffing strategies. We believe such policies should address, among other things, the process and role for integration of healthcare professionals that are locally-designated, such as the Medical Reserve Corps (*https://www.medicalreservecorps.gov/HomePage*), or state-designated, such as Emergency System for Advance Registration of Volunteer Health Professional (ESAR–VHP), (*http://www.phe.gov/esarvhp/pages/home.aspx*) that have assisted in addressing surge needs during prior emergencies. As with previous emergencies, facilities may choose to utilize assistance from the MRC or through the state ESAR–VHP program. We believe the description of healthcare volunteers is already included in the current requirement and does not need to be further defined.

Comment: A commenter questioned if the proposal will require facilities to plan for an electromagnetic event. The commenter noted that protecting against and treating patients after an electromagnetic event is costly.

Another commenter recommended that the rule explicitly include and address the threats of fire, wildfires, tornados, and flooding. The commenter notes that these scenarios are not included in the National Planning Scenarios (NPS).

Response: We expect facilities to develop an emergency preparedness plan that is based on a facility-based and community-based risk assessment using an "all-hazards" approach. If a provider or supplier determines that its facility or community is at risk for an electromagnetic event or natural disasters, such as fires, wildfires, tornados, and flooding, the provider or supplier can choose to incorporate planning for such an event into its emergency preparedness plan. We note that compliance with these requirements, including a determination of whether the provider or supplier based its emergency preparedness plan on facility-based and community-based risk assessments using an all-hazards approach, will be assessed through on-site surveys by CMS, State Survey Agencies, or Accreditation Organizations with CMS-approved accreditation programs.

Comment: A few commenters had recommendations for the structure and organization of the proposed rule. A commenter recommended that CMS specify the 17 providers and supplier types to which the rule would apply in the first part of the rule, so that facilities could verify whether or not the regulations would apply to them. A few commenters suggested that the requirements of the proposed rule should not be included in the CoPs, but instead comprise a separate regulatory chapter specific to emergency preparedness.

Response: We included a list of the provider and supplier types affected by the emergency preparedness requirements in the proposed rule's Table of Contents (78 FR 79083 through 79084) and in the preamble text 78 FR 79090. Thus, we believe that we clearly listed the affected providers and suppliers at the very beginning of the proposed rule.

We also believe the emergency preparedness requirements should be included in the CoPs for providers, the CfCs for suppliers, and requirements for LTC facilities. These CoPs, CfCs, and requirements for LTC facilities are intended to protect public health and safety and ensure that high quality care is provided to all persons. Facilities must meet their respective CoPs, CfCs, or requirements in order to participate in the Medicare and Medicaid programs. We are able to enforce and monitor compliance with the CoPs, CfCs, and requirements for LTC facilities through the survey process. Therefore, we believe that the emergency preparedness requirements are included in the most appropriate regulatory chapters.

Comment: A few commenters suggested additional citations for the proposed rule, recommended that we include specific reference material, and suggested edits to the preamble language. A commenter stated that we omitted some references in the preamble discussion of the proposed rule. The commenter noted that while we included references to HSPD 5, 21, and 8 in the proposed rule, the commenter recommended that all of the HSPDs should have been included. Furthermore, the commenter noted that HSPD 7 in particular, which does not provide a specific role for HHS, should have been referenced since it includes discussion of critical infrastructure protection and the role it plays in all-hazards mitigation.

A commenter suggested that we add the following text to section II.B.1.a. of the proposed rule (78 FR 79085): "HSPD–21 tasked the establishment of the National Center for Disaster Medicine and Public Health (*http://ncdmph.usuhs.edu*) as an academic center of excellence at the Uniformed Services University of the Health Sciences to lead federal efforts in developing and propagating core curricula, training, and research in disaster health."

A commenter recommended that we include the *Joint Guidelines for Care of Children in the Emergency Department,* developed by the American Academy of Pediatrics, the American College of Emergency Physicians, and the Emergency Nurses Association, as a resource for the final rule.

A commenter suggested the addition of the phrase "private critical infrastructure" to the following statement on page 79086 of the proposed rule: "The Stafford Act authorizes the President to provide financial and other assistance to state and local governments, certain private nonprofit organizations, and individuals to support response, recovery, and mitigation efforts."

A commenter included several articles and referenced documentation on emergency preparedness and proper management and disposal of medical waste materials, while another recommended that CMS reference specific FEMA reference documents. Another commenter referred CMS to the Comprehensive Preparedness Guidelines 101 Template, although the commenter did not specify the source of this template.

Response: We thank the commenters for their recommended edits throughout the document. The editorial suggestions are appreciated and noted. We also want to thank commenters for their recommendations for additional resources on emergency preparedness. We provided an extensive list of resources in the proposed and have included links to various resources in this final rule that facilities can use as resources during the development of their emergency preparedness plans. However, we note that these lists are not comprehensive, since we intend to allow facilities flexibility as they implement the emergency preparedness requirements. We encourage facilities to use any resources that they find helpful as they implement the emergency preparedness requirements. Omissions from the list of resources set out in the proposed rule do not indicate any intention on our part to exclude other resources from use by facilities.

Comment: A commenter stated that the local emergency management and public health authorities are the best-placed entities to coordinate their communities' disaster preparedness and response, collaborating with hospitals as instrumental partners in this effort.

Response: We stated in the proposed rule that local emergency management and public health authorities play a very important role in coordinating their community's disaster preparedness and response activities. We proposed that each hospital develop an emergency plan that includes a process for ensuring cooperation and collaboration with local, tribal, regional, state and federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation. We also proposed that hospitals participate in community mock disaster drills. As noted in the proposed rule, we believe that community-wide coordination during a disaster is vital to a community's ability to maintain continuity of healthcare for the patient population during and after a disaster or emergency.

Comment: A few commenters were concerned about the exclusion of specific requirements to account for the health and safety of healthcare workers. A commenter, in reference to pediatric healthcare, recommended that we consider adding a behavioral healthcare provision to the emergency preparedness requirements, which would account for the professional self-care needs of healthcare providers. Another commenter suggested that we change the language on page 79092 of the proposed rule to include 5 phases of emergency management, with the addition of the phrase "protection of the safety and security of occupants in the facility." Another commenter recommended that we include occupational health and safety elements in the four proposed emergency preparedness standards. Furthermore, the commenter recommended that we consult with the Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH), and the Worker Education and Training Program of the National Institute for Environmental Health Sciences (NIEHS) for more information on integrating worker health and safety protections into emergency planning.

Response: While we believe that providers should prioritize the health and safety of their healthcare workers during an emergency, we do not believe that it is appropriate to include detailed requirements within this regulation. As we have previously stated, the regulation is not intended to be overly prescriptive. Therefore, providers have the discretion to establish policies and procedures in their emergency preparedness plans that meet the minimum requirements in this regulation and that are tailored to the specific needs and circumstances of the facility. We note that providers should continue to comply with pertinent federal, state, or local laws regarding the protection of healthcare workers in the workplace.

While it is not within the scope of this rule to address OSHA, NIOSH, or NIEHS work place regulations, we encourage providers and suppliers to consider developing policies and procedures to protect healthcare workers during an emergency. We refer readers to the following list of resources to aid providers and suppliers in the formulation of such policies and procedures:

- *https://www.osha.gov/SLTC/emergencypreparedness/*
- *http://www.cdc.gov/niosh/topics/emergency.html*
- *http://www.niehs.nih.gov/health/topics/population/occupational/index.cfm*

Comment: A few commenters noted that while section 1135 of the Act waives certain Conditions of Participation (CoPs) during a public health emergency, there is no authority to waive the Conditions for Payment (CfPs). The commenters recommended that the Secretary thoroughly review the requirements under the CoPs and the CfPs and seek authority from Congress to waive additional requirements under the CfPs that are burdensome and that affect timely access to care during emergencies.

Response: While we appreciate the concerns of the commenters, these comments are outside the scope of this rule.

1. Integrated Health Systems

In the proposed rule, we proposed that for each separately certified healthcare facility to have an emergency preparedness program that includes an emergency plan, based on a risk assessment that utilizes an all hazards approach, policies and procedures, a communication plan, and a training program.

Comment: We received a few comments that suggested we allow integrated health systems to have one coordinated emergency preparedness program for the entire system.

Commenters explained that an integrated health system could be comprised of two nearby hospitals, a LTC facility, a HHA, and a hospice. The commenters stated that under our proposed regulation, each entity would need to develop an individual emergency preparedness program in order to be in compliance. Commenters proposed that we allow for the development of one universal emergency preparedness program that encompasses one community-based risk assessment, separate facility-based risk assessments, integrated policies and procedures that meet the requirements for each facility, and coordinated communication plans, training and testing. They noted that allowing for a coordinated emergency preparedness program would ultimately reduce the burden placed on the individual facilities and provide for a more coordinated response during an emergency.

Response: We appreciate the comments received on this issue. We agree that allowing integrated health systems to have a coordinated emergency preparedness program is in the best interest of the facilities and patients that comprise a health system. Therefore, we are revising the proposed requirements by adding a separate standard to the provisions applicable to each provider and supplier type. This separate standard will allow any separately certified healthcare facility that operates within a healthcare system to elect to be a part of the healthcare system's unified emergency preparedness program. If a healthcare system elects to have a unified emergency preparedness program, this integrated program must demonstrate that each separately certified facility within the system actively participated in the development of the program. In addition, each separately certified facility must be capable of demonstrating that they can effectively implement the emergency preparedness program and demonstrate compliance with its requirements at the facility level.

As always, each facility will be surveyed individually and will need to demonstrate compliance. Therefore, the unified program will also need to be developed and maintained in a manner that takes into account the unique circumstances, patient populations, and services offered for each facility within the system. For example, for a unified plan covering both a hospital and a LTC facility, the emergency plan must account for the residents in the LTC facility as well as those patients within a hospital, while taking into consideration the difference in services that are provided at a LTC facility and a hospital. In addition, the healthcare system will need to take into account the resources each facility within the system has and any state laws that the facility must adhere to. The unified emergency preparedness program must also include a documented community–based risk assessment and an individual facility-based risk assessment for each separately certified facility within the health system, both utilizing an all-hazards approach. The unified program must also include integrated policies and procedures that meet the emergency preparedness requirements specific to each provider type as set forth in their individual set of regulations. Lastly, the unified program must have a coordinated communication plan and training and testing program. We believe that this approach will allow a healthcare system to spread the cost associated with training and offer a financial advantage to each of the facilities within a system. In addition, we believe that, in some cases this approach will provide flexibility and could potentially result in a more coordinated response during an emergency that will enable a more successful outcome.

2. Requests for Technical Assistance and Funding

The December 2013 proposed rule included an appendix of the numerous resources and documents used to develop the proposed rule. Specifically, the appendix to the proposed rule included helpful reports, toolkits, and samples from multiple government agencies such as ASPR, the CDC, FEMA, HRSA, AHRQ, and the Institute of Medicine (See Appendix A, 78 FR 79198). In response to our proposed rule, we received numerous comments requesting that we provide facilities with increased funding and technical assistance to implement our proposed regulations.

Comment: A few commenters appreciated the resources that we provided in the proposed rule, but expressed concerns that, despite the resources referenced in the regulation, busy and resource-constrained facilities will not have a simple and organized way to access technical assistance and other valuable information in order to comply with the proposed requirements. Commenters indicated that despite the success of healthcare coalitions, they have not been established in every region.

Commenters suggested that formal technical assistance should be available to facilities to help them successfully implement their emergency preparedness requirements. A commenter recommended that ASPR should lead this effort given its expertise in emergency preparedness planning and its charge to lead the nation in preventing, preparing for, and responding to the adverse health effects of public health emergencies. Another commenter suggested that we consider hosting regional meetings for facilities to share information and resources and that we provide region specific resources on our Web site. Commenters encouraged CMS to promote collaborative planning among facilities and provide the support needed for facilities to leverage each other's resources. These commenters believe that networks of facilities will be in a better position than governmental resources to identify cost and time saving efficiencies, but need support from CMS to coordinate their efforts.

Response: We appreciate the feedback from commenters and understand how valuable guidance and resources will be to providers and suppliers in order to comply with this regulation. We do not anticipate providing formal technical assistance, such as CMS-led trainings, to providers and suppliers. Instead, as with all of our regulations, we will release interpretive guidance for this regulation that will aid facilities in implementing these regulations and provide information regarding best practices. We strongly encourage facilities to review the interpretative guidance from us, use the guidance to identify best practices, and then network with other facilities to develop strategic plans. Providers and suppliers impacted by this regulation should collaborate and leverage resources in developing emergency preparedness programs to identify cost and time saving efficiencies. We note that in this final rule we have revised the proposed requirements to allow integrated health systems to elect to have one unified emergency preparedness program (see Section II.A.1.Intergrated Health Systems for a detailed discussion of the requirement). We believe that collaborative planning will not only leverage the financial burden on facilities, but also result in a more coordinated response to an emergency event.

In addition, we note that in the proposed rule, we indicated numerous resources related to emergency preparedness, including helpful reports, toolkits, and samples from ASPR, the CDC, FEMA, HRSA, AHRQ, and the Institute of Medicine (See Appendix A, 78 FR 79198). Providers and suppliers should use these many resources as templates and the framework for getting their emergency preparedness programs started. We also refer readers to SAMHSA's Disaster Technical Assistance Center (DTAC) for more information on delivering an effective mental health and substance abuse (behavioral health) response to disasters at *http://www.samhsa.gov/dtac/*.

Finally we note that ASPR, as a leader in healthcare system preparedness, developed and launched the Technical Resources, Assistance Center, and Information Exchange (TRACIE). TRACIE is designed to provide resources and technical assistance to healthcare system preparedness stakeholders in building a resilient healthcare system. There are numerous products and resources located within the TRACIE Web site that target specific provider types affected by this rule. While TRACIE does not focus specifically on the requirements implemented in this regulation, this is a valuable resource to aid a wide spectrum of partners with their health system emergency preparedness activities. We strongly encourage providers and suppliers to utilize TRACIE and leverage the information provided by ASPR.

Comment: Some commenters noted that their region is currently experiencing a reduction in the federal funding they receive through the HPP. These commenters stated that the HPP program has proven to be successful and encouraged healthcare entities impacted by this regulation to engage their state HPP for technical assistance and training while developing their emergency preparedness programs. Commenters shared that HPP staff have established trusting and fundamental relationships with facilities, associations, and emergency managers throughout their state. Commenters expressed that while the program has been instrumental in supporting their state's healthcare emergency response, it does not make sense to impose these new emergency preparedness regulations while financial resources through the HPP are diminishing. Commenters stressed that the HPP program alone cannot support the rollout of these new regulations and emphasized that a strong and well-funded HHP program is needed to contribute to the successful implementation of these new requirements. Commenters also suggested that CMS offer training to the states' HPP programs, so that these agencies can remain in a central leadership role within their states.

Response: We appreciate the feedback and agree that the HPP program has been a fundamental resource for developing healthcare emergency preparedness programs. While we recognize that HPP funding is limited, we want to emphasize that the HPP program is not intended to solely fund a facility's individual emergency preparedness program and activities. Despite the limited financial resources, healthcare facilities should continue to engage their healthcare coalitions and state HPP coordinators for training and guidance. We encourage healthcare facilities, particularly those in neighboring geographic areas, to collaborate and build relationships that will allow facilities to share and leverage resources.

Comment: A few commenters noted that, while these new emergency preparedness regulations should be put in place to protect vulnerable communities, there should also be incentives to help facilities meet these new standards. Many commenters expressed concerns about the decrease in funding available to state and local governments. Most commenters recommended that grant funding and loan programs be provided to support hiring staff to develop or modify emergency plans. However, a few commenters suggested that federal funding should be allocated to the nation's most vulnerable counties. These commenters believe that special federal funding consideration should not be provided to all, but rather should be given to those counties and cities with a uniquely dense population. A commenter believed that incentives should be put in place to reward those facilities that are found compliant with the new standards. In addition, several commenters requested that CMS provide additional Medicare payment to providers and suppliers for implementing these emergency preparedness requirements.

Response: We currently expect facilities to have and develop policies and procedures for patient care and the overall operations. The emergency preparedness requirement may increase costs in the short term because resources will have to be devoted to the assessment and development of an emergency plan utilizing an all-hazards approach. While the requirements could result in some immediate costs to a provider or supplier, we believe that developing an emergency preparedness program will overall be beneficial to any provider or supplier. In addition, planning for the protection and care of patients, clients, residents, and staff during an emergency or a disaster is a good business practice. As we have previously noted, CMS has the authority to create and modify health and safety CoPs, which establish the requirements that a provider must meet in order to participate in the Medicare or Medicaid programs.

3. Requirement To Track Patients and Staff

In the proposed rule, we requested comments on the feasibility of tracking staff and patients in outpatient facilities.

Comment: Overall commenters agreed that there is not a crucial need for outpatient facilities to track their patients as compared to inpatient facilities. Commenters noted that outpatient providers and suppliers would most likely close their facilities prior to or immediately after an emergency, sending staff and patients home. We did not propose the tracking requirement for transplant centers, CORFs, Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services, and RHCs/FQHCs. For OPOs we proposed that they would only need to track staff. We stated that transplant centers' patients and OPOs' potential donors would be in hospitals, and thus, would be the hospital's responsibility.

Response: We agree with the majority of commenters and continue to believe that it is impractical for outpatient providers and suppliers to track patients and staff during and after an emergency. In the event of an emergency outpatient providers and suppliers will have the flexibility to cancel appointments and close their facilities. Therefore, we are finalizing the rule as proposed. Specifically, we do not require transplant centers, RHCs/FQHCs, CORFs, Clinics, Rehabilitation Agencies, and Public Health Agencies as providers of Outpatient Physical Therapy and Speech-Language Pathology Services to track their patients and staffs. We are also finalizing our proposal for OPOs to track staff only both during and after an emergency. A detailed discussion of comments specific to OPOs tracking staff can be found in section II.Q. of this final rule (Emergency Preparedness Regulations for Organ Procurement Organizations).

Comment: In addition to the feedback we received on whether we should require outpatient providers and suppliers to track their patients and staff, we also received varying comments in regards to the providers and suppliers that we did propose to meet the tracking requirement.Commenters supported the proposal for certain providers and suppliers to track staff and patients, and agreed that a system is needed. Some understood that the information about staff and patient location would be needed during an emergency, but stated that it would be burdensome and often unrealistic to expect providers and suppliers to locate individuals after an emergency event. Some commenters noted that patients at a receiving facility would be the responsibility of the receiving facility. Some commenters stated that tracking of patients going home is not their responsibility, or would be difficult to achieve. A commenter believed that tracking of staff would be a violation of staff's privacy. A commenter stated that in their large facility, only the "staff on duty" at the time of the emergency would be in their staffing system. Some commenters stated that staff would be difficult to track because some facilities have hundreds or thousands of employees, and some staff may have left to be with their families. Some commenters suggested that CMS promote the use of voluntary registries to help track their outpatient populations and encouraged coordination of these registries among facility types. A few commenters stated that one of the tools discussed in the preamble for tracking patients; namely, The Joint Patient Assessment and Tracking System (JPATS) was only available for hospitals and did not include other providers such as LTC facilities, and several stated the system is incompatible with their IT systems.

Response: For RNHCIs, PRTFs, PACE organizations, LTC facilities, ICFs/IID, hospitals, and CAHs, we proposed that these providers develop policies and procedures regarding a system to track the location of staff and patients in the hospital's care both during and after an emergency. Despite providing services on an outpatient basis, we also proposed to require hospices, HHAs, and ESRD facilities to assume this responsibility because these providers and suppliers would be required to provide continuing patient care during an emergency. We also proposed the tracking requirement for ASCs because we believed an ASC would maintain responsibility for their staff and patients if patients were in the facility.

After carefully analyzing the issues raised by commenters regarding the process to track staff and patients during and after an emergency, we agree with the commenters that our proposed requirements could be unnecessarily burdensome. We are revising the tracking requirements based on the type of facility. For CAHs, Hospitals, and RNHCIs we are removing the proposed requirement for tracking after an emergency. Instead, in this final rule we require that these facilities must document the specific name and location of the receiving facility or other location for patients who leave the facility during the emergency. We would expect facilities to track their on-duty staff and sheltered patients during an emergency and indicate where a patient is relocated to during an emergency (that is, to another facility, home, or alternate means of shelter, etc.).

Also, since providers and suppliers are required to conduct a risk assessment and develop strategies for addressing emergency events identified by the risk assessment, we would expect the facility to include in its emergency plan a method for contacting off-duty staff during an emergency and procedures to address other contingencies in the event staff are not able to report to duty which may include but are not limited to staff from other facilities and state or federally-designated health professionals.

For PRTFs, LTC facilities, ICF/IIDs, PACE organizations, CMHCs, and ESRD facilities we are finalizing as proposed the requirement to track staff and patients both during and after an emergency. We have clarified that the requirement applies to tracking on-duty staff and sheltered patients. Furthermore, we clarify that if on-duty staff and sheltered patients are relocated during the emergency, the provider or supplier must document the specific name and location of the receiving facility or other location. Unlike inpatient facilities, PRTFs, ICF/IIDs, and LTC facilities are residential facilities and serve as the patient's home, which is why in these settings we refer to the patients as "residents." Similar to these residential facilities ESRD facilities, CMHCs, and PACE organizations, provide a continuum of care for their patients. Residents and patients of these facilities would anticipate returning to these facilities after an emergency. For this reason, we believe that it is imperative for these facilities to know where their residents/patients and staff are located during and after the emergency to allow for repatriation and the continuation of regularly scheduled appointments.

While we pointed out JPATS as a tool for providers and suppliers, we note that we indicated that we were not proposing a specific type of tracking system that providers and suppliers must use. We also indicated that in the proposed rule that a number of states have tracking systems in place or under development and the systems are available for use by healthcare providers and suppliers. We encourage providers and suppliers to leverage the support and resources available to them through local and national healthcare systems, healthcare coalitions, and healthcare organizations for resources and tools for tracking patients.

We have also reviewed our proposal to require ASCs, hospices, and HHAs to track their staff and patients before and after an emergency. We discuss in detail the comments we received specific to these providers and suppliers and revisions to their proposed tracking requirement in their specific section later in this final rule.

B. Implementation Date

We proposed several variations on an implementation date for the emergency preparedness requirements (78 FR 79179). Regarding the implementation date, we requested information on the following issues:

- A targeted approach to emergency preparedness that would apply the rule to one provider or supplier type or a subset of provider types, to learn from implementation prior to requiring compliance for all 17 types of providers and suppliers.
- A phased-in approach that would implement the requirements over a longer time horizon, or differential time horizons for the different provider and supplier types.

Comment: Most commenters recommended that CMS set a later implementation date for the emergency preparedness requirements. Some commenters recommended that we use a targeted approach, whereby the rule would be implemented first by one provider/supplier type or a subset of provider/supplier types, with later implementation by other provider/supplier types, so they can learn from prior implementation at other facilities. Others recommended that CMS phase in the requirements over a longer time horizon.

Many commenters recommended that CMS require implementation at hospitals or LTC facilities first, so that other facilities could benefit from the experience and lessons learned by these providers. Some of these commenters stated that these providers have the most capacity to implement these requirements. A commenter recommended that hospitals implement the requirements of the rule first, followed by CAHs and other inpatient provider types and LTC facilities. Other provider and supplier types would follow thereafter. The commenter recommended that CMS establish a period of non-enforcement for each implementation phase, while a Phase 1 evaluation is conducted and feedback is given to other facilities.

Several commenters, including major hospital associations, disagreed with CMS' proposal to implement all of the requirements 1 year after the final rule is published. The commenters noted that implementation of all the requirements after 1 year would be burdensome and costly to many facilities. In addition, a few commenters noted that certain facilities, mainly rural and small facilities, may be at a disadvantage because they have not participated in national emergency preparedness planning efforts or because they lack the necessary resources to implement emergency preparedness plans.

A few commenters drew a distinction between accredited and non-accredited facilities and recommended that hospitals implement the requirements within a year or 2 after publication of the final rule. Some of the commenters noted that non-accredited facilities, CAHs, HHAs, and hospices, would need more time. Several of these commenters also stated that hospitals that need more time for implementation should be able to propose to CMS a reasonable period of time to comply. A few commenters stated that the emergency preparedness proposal is unlike the standards utilized by the TJC and that enforcement of these requirements should be at a later date for both accredited and non-accredited facilities.

Some commenters recommended that CMS give ASCs and FQHCs additional time to come into compliance. A commenter recommended that CMS set a later implementation date for the requirements and provide a flexible implementation timeframe based on provider type and resources. A few commenters stated that the implementation timeline is too short for rehabilitation facilities, long-term acute care facilities, LTC facilities, behavioral health inpatient facilities, and ICF/IIDs.

A few commenters recommended that CMS phase-in implementation on a standard-by-standard basis. A commenter recommended that LTC facilities implement the requirements 12 to 18 months after hospitals. Furthermore, the commenter recommended an 18 to 24 month phase-in of emergency systems and a 24 to 38 month phase-in for the training and testing requirements. Another commenter recommended that facilities be allowed to comply with the initial planning requirements within 2 years, and then be allowed to comply with the subsistence and infrastructure requirements in years 3 and 4.

The commenters varied in their recommendations on the timeframe CMS should use for the implementation date. These recommendations ranged from 6 months to 5 years, with a few commenters recommending even longer periods. Some commenters noted that applying a targeted approach, covering one or a subset of provider classes to learn from implementation prior to extending the rule to all groups, would also allow a longer period of time for other provider/supplier types to prepare for implementation. Furthermore, a commenter noted that a phased in approach would help to alleviate the cost burden on facilities that would need to create an emergency plan and train and test staff.

Response: We appreciate the commenters' feedback. We considered a phased-in approach in a number of ways. We looked at phasing in the implementation of various providers and suppliers; and phasing in the various standards of the regulation. We concluded that this approach would be too difficult to implement, enforce, and evaluate. Also, this would not allow communities to have a comprehensive approach to emergency preparedness. However, we agree that there should be a later implementation date for the emergency preparedness requirements. However, we do not believe that a targeted or phased-in approach to implementation is appropriate. One thing we proposed and are now finalizing to address this concern is extending the implementation timeframe for the requirements to 1 year after the effective date of this final rule (see section section II, Provisions of the Proposed Rule and Responses to Public Comments, part B, Implementation Date). We believe it is imperative that each provider thinks in terms broader than their own facility, and plan for how they would serve similar and other healthcare facilities as well as the whole community during and surrounding an emergency event. To encourage providers to develop a comprehensive and coordinated approach to emergency preparedness, all providers need to adopt the requirements in this final rule at the same time.

Commenters have stated that hospitals that are TJC-accredited are part of the Hospital Preparedness Program (HPP) program, and those hospitals that follow National Fire Protection Association (NFPA®) standards, have already established most of the emergency preparedness requirements set out in this rule. Based on CDC's National Health Statistics Reports; Number 37, March 24, 2011, page 2 (NCHS–2008PanFluand EP_NHAMCSSurveyReport_2011.pdf), about 67.9 percent of hospitals had plans for all six hazards (epidemic-pandemic, biological, chemical, nuclear-radiological, explosive-incendiary, and natural incidents). Nearly all hospitals (99.0 percent) had emergency response plans that specifically addressed chemical accidents or attacks, which were not significantly different from the prevalence of plans for natural disasters (97.8 percent), epidemics or pandemics (94.1 percent), and biological accidents or attacks. However, we also believe that other facilities will be ready to begin implementation of these rules at the same time as hospitals. We believe that most facilities already have some basic emergency preparedness requirements that can be built upon to meet the requirements set out in this final rule. We note that we have modified or eliminated some of our proposed requirements for certain providers and suppliers, as discussed later in this final rule, which should ease concerns about implementation. Therefore, we believe that all affected providers and suppliers will be able to comply with these requirements 1 year after the final rule is published.

We do not believe a period of non-enforcement is appropriate as it will further prolong the implementation of necessary and life-saving emergency preparedness planning requirements by facilities. A later implementation date will leave the most vulnerable patient populations and unprepared facilities without a valuable, life-saving emergency preparedness plan should an emergency arise. We have not received comments that persuaded us that a later implementation date for these requirements of more than 1 year is beneficial or appropriate for providers and suppliers or their patients.

In response to commenters that opposed our proposal to implement the requirements 1 year after the final rule was published and recommended that we afford facilities more time to implement the requirements, we do not believe that the requirements will be overly burdensome or overly costly to providers and suppliers. We note, as we have heard from many commenters, that many facilities already have established emergency preparedness plans, as required by accrediting organizations. However, we acknowledge that there may be a significant amount of work that small facilities and those with limited resources will need to undertake to establish an emergency preparedness plan that conforms to the requirements set out in this regulation. However, we believe that prolonging the requirements in this final rule by 1 year will provide sufficient time for implementation among the various facilities to meet the emergency preparedness requirements. We encourage facilities to engage and collaborate with their local partners and healthcare coalitions in their area for assistance. Facilities may also access ASPR's TRACIE web portal, which is a healthcare emergency preparedness information gateway that helps stakeholders at the federal, state, local, tribal, non-profit, and for-profit levels have access to information and resources to improve preparedness, response, recovery, and mitigation efforts. ASPR TRACIE, located at: *https://asprtracie.hhs.gov/*, is an excellent resource for the various CMS providers and suppliers as they seek to implement the enhanced emergency preparedness requirements. We encourage facilities to engage and collaborate with their local partners and healthcare coalitions in their area for technical assistance as they include local experts and can provide regional information that can inform the requirements as set forth.

Comment: Some commenters recommended that CMS implement all of the emergency preparedness requirements 1 year after the final rule is published. Other commenters recommended that CMS implement the requirements as soon as the final rule is published or set an implementation date that is less than 1 year from the effective date of this final rule. A few of these commenters, including a major beneficiary advocacy group, stated that implementation should begin as soon as practicable, or immediately after the final rule is published and cautioned against a later implementation date that may leave facilities without important emergency preparedness plans during an emergency.

Some of these commenters stated that hospitals in particular already have emergency preparedness plans in place and are well equipped and prepared to implement the requirements set out in these regulations over the course of a year. Some commenters noted that most hospitals are fully aware of the 4 emergency preparedness requirements set out in the proposed rule through current accreditation standards. Furthermore, the commenters noted that these four requirements would not impose any additional burdens on hospitals. A few commenters acknowledged that some hospitals are not under the purview of an accrediting agency and therefore may need up to 1 year to implement the requirements.

Response: We appreciate the commenters' feedback. We agree with the commenters' view that implementation of the requirements should occur 1 year after the final rule is published for all 17 types of providers and suppliers. We believe that an implementation date for these requirements that is 1 year after the effective date of this final rule will allow all facilities to develop an emergency preparedness plan that meets all of the requirements set out within these regulations. While we understand why some commenters would want these requirements to be implemented shortly after publication of the final rule, we also understand some commenters' concerns about that timeframe. We believe that facilities will need a period of time after the final rule is published to plan, develop, and implement the emergency preparedness requirements in the final rule. Accordingly, we believe that 1 year is a sufficient amount of time for facilities to meet these requirements.

Comment: A few commenters recommended that CMS include a provision that would allow facilities to apply for additional time extensions or waivers for implementation. A commenter recommended that CMS allow facilities to rely on their existing policies if the facility can demonstrate that the existing policies align with the emergency preparedness plan requirements and achieve a similar outcome.

Response: We do not agree with including a provision that will allow for facilities to apply for extensions or waivers to the emergency preparedness requirements. We believe that an implementation date that is beyond 1 year after the effective date of this final rule for these requirements is inappropriate and leaves the most vulnerable facilities and patient populations without life-saving emergency preparedness plans.

However, we do understand that some facilities, especially smaller and more rural facilities, may experience difficulties developing their emergency preparedness plans. Therefore, we believe that setting an implementation date of 1 year after the effective date of this final rule for these requirements will give these and other facilities sufficient time for compliance. As stated earlier, we encourage facilities to form coalitions in their area for assistance in meeting these requirements. We also encourage facilities to utilize the many resources we have included in the proposed and final rule.

We appreciate that some facilities have existing emergency preparedness plans. However, all facilities will be required to develop and maintain an emergency preparedness plan based on an all-hazards approach and address the four major elements of emergency preparedness in their plan that we have identified in this final rule. Each facility will be required to evaluate its current emergency preparedness plan and activities to ensure that it complies with the new requirements.

Comment: A few commenters recommended that CMS implement enforcement of the final rule when the interpretive guidance (IG) is finalized by CMS. A few commenters noted that this implementation data should include a period of engagement with hospitals and other providers and suppliers, a period to allow for the development and testing of surveyor tools, and a readiness review of state survey agencies that is complete and publicly available. A commenter recommended that facilities implement the requirements 5 years after the IGs have been published. Another commenter recommended that CMS phase-in implementation in terms of enforcement and roll out, allowing time for full implementation and assistance to facilities and state surveyors.

A few commenters recommended that providers be allowed a period of time where they are held harmless during a transitional planning period, where providers may be allotted more time to plan and implement the emergency preparedness requirements.

Response: We disagree with the commenter's recommendations that we should implement this regulation after the IGs have been published. Additionally, we disagree with the recommendation that CMS phase in enforcement or hold facilities harmless for a period of time while the requirements are being implemented, and we do not believe that it is appropriate to implement the CoPs after the IGs are established. The IGs are subregulatory guidelines which establish our expectations for the function states perform in enforcing the regulatory requirements. Facilities do not require the IGs in order to implement the regulatory requirements. We note that CMS historically releases IGs for new regulations *after* the final rule has been published. This EP rule is accompanied by extensive resources that providers and suppliers can use to establish their emergency preparedness programs. In addition, CMS will create a designated Web site for the Emergency Preparedness Rule at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/index.html* that will house information for providers, suppliers and surveyors. The Web site will contain the link to the final rule and will also include templates, provider checklists, sample emergency preparedness plans, disaster specific information and lessons learned. CMS will also be releasing an all-hazards FAQ document that will be posted to Web site as well. We will also continue to communicate with providers and other stakeholders about these requirements through normal channels. For example we will communicate with surveyors via Survey and Certification memoranda and provide information to facilities via, provider forums, press releases and Medicare Learning Network publications. We continue to believe that setting a later implementation date for the enforcement of these requirements will leave the most vulnerable patient populations and unprepared facilities without valuable, life-saving emergency preparedness plans should an emergency arise. One year is a sufficient amount of time for facilities to meet these requirements.

Comment: Several commenters, including national and local organizations, and providers, supported using a transparent process in the development of interpretive guidelines for state surveyors. They suggested consulting with industry experts, healthcare organizations, accrediting bodies and state survey agencies in the development of clear and concise interpretation and application of the IGs nationwide. One provider suggested that CMS post the draft guidance electronically for a period of time and provide an email address for stakeholders to offer comments. Furthermore, this provider suggested that the guidance be pilot-tested and revised prior to adoption.

Response: We thank the commenters for their suggestions. In addition to the CoPs/CfCs, IGs will be developed by CMS for each provider and supplier types. We also note that surveyors will be provided training on the emergency preparedness requirements so that enforcement of the rule will be based on the regulations set forth here. While comments on the process for developing the interpretive guidelines is outside the scope of this proposed rule, we agree that consistency and conciseness in the IGs is critical in the evaluation process for providers and suppliers in meeting these emergency preparedness requirements.

Comment: A few commenters recommended that CMS allow multiple facility types that are administered by the same owner to obtain waivers of specific requirements or have a single multi-facility plan approved, if they can collectively adopt a functionally equivalent strategy based on the requirements that may apply to one of their facility types. The commenters note that operation of more than one facility type is not uncommon among Tribal health programs.

Response: Although we disagree with the commenter's recommendation that we allow multiple facility types that are administered by the same owner to obtain implementation waivers of specific requirements, we agree that multiple facilities that are administered by the same owner, that effectively operate as an integrated health system, can have a unified emergency preparedness program. We previously discussed this final policy in the Integrated Health System section of this final rule.

Comment: A commenter recommended that the states take the lead on determining the timing of implementation for various providers and suppliers.

Response: We do not believe that State governments or State agencies should determine the timing of implementation for facilities' emergency preparedness plans. While the State government will provide valuable resources during a disaster, CMS is responsible for the implementation of the federal regulations for Medicare and Medicaid certified providers and suppliers. Furthermore, it will be difficult for survey agencies to monitor the requirements in this rule if each State has different implementation timelines. As stated previously, we believe that most providers have basic emergency preparedness plans and protocols and that they are capable of implementing the requirements within 1 year after the final rule is published.

After consideration of the comments received, we are finalizing our proposal, without modification, to require implementation of all of the requirements for all providers and suppliers 1 year after the final rule is published.

C. Emergency Preparedness Regulations for Hospitals (§ 482.15)

Our proposed hospital regulatory scheme was the basis for all other proposed emergency preparedness requirements as set out in the proposed rule. Since application of the proposed regulatory language for hospitals would be inappropriate or overly burdensome for some facilities, we tailored specific proposed requirements to each providers' and suppliers' unique situation. In the December 2013 proposed rule we provided a detailed discussion of each proposed hospital requirement, as well as resources that facilities could use to meet the proposed requirements, a methodology to establish and maintain emergency preparedness, and links to guidance materials and toolkits that could be used to help meet the requirements. We encourage readers to refer to the proposed rule for this detailed discussion.

As previously discussed, many commenters commented on the proposed regulations for hospitals, but indicated that their comments could also be applied to the additional provider and supplier types. Therefore, where appropriate, we collectively refer to hospitals and the other providers and suppliers as "facilities" in this section of the final rule.

1. Risk Assessment and Emergency Plan (§ 482.15(a))

Section 1861(e) of the Act defines the term "hospital" and subsections (1) through (8) list requirements that a hospital must meet to be eligible for Medicare participation. Section 1861(e)(9) of the Act specifies that a hospital must also meet such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution. Under the authority of 1861(e) of the Act, the Secretary has established in regulations at 42 CFR part 482 the requirements that a hospital must meet to participate in the Medicare program.

Section 1905(a) of the Act provides that Medicaid payments may be applied to hospital services. Regulations at §§ 440.10(a)(3)(iii) and 440.140 require hospitals, including psychiatric hospitals, to meet the Medicare CoPs to qualify for participation in Medicaid. The hospital and psychiatric hospital CoPs are found at §§ 482.1 through 482.62.

Services provided by hospitals encompass inpatient and outpatient care for persons with various acute or chronic medical or psychiatric conditions, including patient care services provided in the emergency department. Hospitals are often the focal points for healthcare in their respective communities; thus, it is essential that hospitals have the capacity to respond in a timely and appropriate manner in the event of a natural or man-made disaster. Additionally, since Medicare-participating hospitals are required to evaluate and stabilize every patient seen in the emergency department and to evaluate every inpatient at discharge to determine his or her needs and to arrange for post-discharge care as needed, hospitals are in the best position to coordinate emergency preparedness planning with other providers and suppliers in their communities.

We proposed a new requirement under § 482.15 that would require hospitals to have both an emergency preparedness program and an emergency preparedness plan. To ensure that all hospitals operate as part of a coordinated emergency preparedness system, we proposed at § 482.15 that all hospitals establish and maintain an emergency preparedness plan that complies with both federal and state requirements. Additionally, we proposed that the emergency preparedness plan be reviewed and updated at least annually. As part of an annual review and update, staff are required to be trained and be familiar with many policies and procedures in the operation of their facility and are held responsible for knowing these requirements. Annual reviews help to refresh these policies and procedures which would include any revisions to them based on the facility experiencing an emergency or as a result of a community or natural disaster.

In keeping with the focus of the emergency management field, we proposed that prior to establishing an emergency preparedness plan, the hospital and all other providers and suppliers would first perform a risk assessment based on using an "all-hazards" approach. Rather than managing planning initiatives for a multitude of threat scenarios all-hazards planning focuses on developing capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters. Thus, all-hazards planning does not specifically address every possible threat but ensures those hospitals and all other providers and suppliers will have the capacity to address a broad range of related emergencies.

We stated that it is imperative that hospitals perform all-hazards risk assessment consistent with the concepts outlined in the National Preparedness System, published by the United States (U.S.) Department of Homeland Security, as well as guidance provided by Agency for Healthcare Research and Quality (AHRQ), to help hospital planners and administrators make important decisions about how to protect patients and healthcare workers and assess the physical components of a hospital when a natural or manmade disaster, terrorist attack, or other catastrophic event threatens the soundness of a facility. We also provided additional guidance and resources for assistance with designing and performing a hazard vulnerability assessment.

In the proposed rule (78 FR 79094), we stated that in order to meet the proposed requirement for a risk assessment at § 482.15(a)(1), we would expect hospitals to consider, among other things, the following: (1) Identification of all business functions essential to the hospitals operations that should be continued during an emergency; (2) identification of all risks or emergencies that the hospital may reasonably expect to confront; (3) identification of all contingencies for which the hospital should plan; (4) consideration of the hospital's location, including all locations where the hospital delivers patient care or services or has business operations; (5) assessment of the extent to which natural or man-made emergencies may cause the hospital to cease or limit operations; and (6) determination of what arrangements with other hospitals, other healthcare providers or suppliers, or other entities might be needed to ensure that essential services could be provided during an emergency.

We proposed at § 482.15(a)(2) that the emergency plan include strategies for addressing emergency events identified by the risk assessment. For example, a hospital in a large metropolitan city may plan to utilize the support of other large community hospitals as alternate care placement sites for its patients if the hospital needs to be evacuated. However, we would expect the hospital to have back-up evacuation plans for circumstances in which nearby hospitals also were affected by the emergency and were unable to receive patients.

At § 482.15(a)(3), we proposed that a hospital's emergency plan address its patient population, including, but not limited to, persons at-risk. We also discussed in the preamble of the proposed rule that "at-risk populations" are individuals who may need additional response assistance, including those who have disabilities, live in institutionalized settings, are from diverse cultures, have limited English proficiency or are non-English speaking, lack transportation, have chronic medical disorders, or have pharmacological dependency. According to the section 2802 of the PHS Act (42 U.S.C. 300hh–1) as added by Pandemic and All-Hazards Preparedness Act (PAHPA) in 2006, in "at-risk individuals" means children, pregnant women, senior citizens and other individuals who have special needs in the event of a public health emergency as determined by the Secretary. In 2013, the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) amended the PHS Act (*http://www.gpo.gov/fdsys/pkg/PLAW-113publ5/pdf/PLAW-113publ5.pdf*) and added that consideration of the public health and medical needs of "at-risk individuals" includes taking into account the unique needs and considerations of individuals with disabilities. The National Response Framework (NRF), the primary federal document guiding how the country responds to all types of disasters and emergencies, includes in its description of "at-risk individuals" children, individuals with disabilities and others with access and functional needs; those from religious, racial and ethnically diverse backgrounds; and people with limited English proficiency. We have included additional examples of at-risk populations, including definitions from both PHS Act and NRF and have expanded the definition to include examples used in the healthcare industry. We have stated that the patient population may not be limited to just persons at-risk but may include, for example, descriptions of patient populations unique to their geographical areas, such as CMHCs and PRTFs. The definition of at-risk populations provided in the regulation text is to include all of the populations discussed in the NRF and PHS Act definitions and are defined within the individual providers and suppliers included in this regulation.

We also proposed at § 482.15(a)(3) that a hospital's emergency plan address the types of services that the hospital would be able to provide in an emergency. In regard to emergency preparedness planning, we also proposed at § 482.15(a)(3) that all hospitals include delegations and succession planning in their emergency plan to ensure that the lines of authority during an emergency are clear and that the plan is implemented promptly and appropriately.

Finally, at § 482.15(a)(4), we proposed that a hospital have a process for ensuring cooperation and collaboration with local, tribal, regional, state, or federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation, including documentation of the hospital's efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts. We stated that we believed planning with officials in advance of an emergency to determine how such collaborative and cooperative efforts would achieve and foster a smoother, more effective, and more efficient response in the event of a disaster. Providers and suppliers must document efforts made by the facility to cooperate and collaborate with emergency preparedness officials.

Comment: A few commenters stated that the term "all-hazards" is too broad and instead should be geared towards possible emergencies in their geographical area. The commenters stated that the term "all-hazards" should be replaced with "Hazard Vulnerability Assessment" (HVA) to be more in line with the current emergency preparedness industry language that providers and suppliers are more familiar. Commenters suggested that CMS align the final rule with the current requirements of accreditation organizations. Some commenters requested clarification as to what an HVA is and how it is performed. Furthermore, commenters encouraged us to discuss the risks or emergencies that a hospital may expect to confront. They recommended adding language to require that the hospital's emergency plan be based on an HVA utilizing an all-hazards approach that identifies the emergencies that the hospital may reasonably expect to confront.

Response: In "An All Hazards Approach to Vulnerable Populations Planning" by Charles K.T. Ishikawa, MSPH, Garrett W. Simonsen, MSPS, Barbara Ceconi, MSW, and Kurt Kuss, MSW (see *https://apha.confex.com/apha/135am/webprogram/Paper160527.html*), the researchers described an all hazards planning approach as "a more efficient and effective way to prepare for emergencies. Rather than managing planning initiatives for a multitude of threat scenarios, all hazards planning focuses on developing capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters." Thus, all-hazards planning does not specifically address every possible threat but ensures that hospitals and all other providers will have the capacity to address a broad range of related emergencies. In the proposed rule, we referred to a "hazard vulnerability risk assessment" as a "risk assessment" that is performed using an all-hazards approach. However, we understand that some providers use the term "hazard vulnerability assessment "(HVA) while other providers and federal agencies use terms such as "all-hazards self-assessment" or "all-hazards risk assessment" to describe the process by which a provider will assess and identify potential gaps in its emergency plan(s). The providers and suppliers discussed in this regulation should utilize an all-hazards approach to perform a "hazard vulnerability risk assessment." While those providers and suppliers that are more advanced in emergency preparedness will be familiar with some of the industry language, we believe that some providers/suppliers might not have a working knowledge of the various terms; therefore, we used language defining risk assessment activities that would be easily understood by all providers and suppliers that are affected by this regulation and align with the national preparedness system and terminology.

Comment: We received many comments on our proposed changes to require hospitals to develop an emergency plan utilizing an all-hazards approach based on a facility- and community-based risk assessment from individuals, national and state professional organizations, accreditation organizations, individual and multi-hospital systems, and national and state hospital organizations.

Some commenters recommended adding "local" after applicable federal and state emergency preparedness requirements since some states already have local laws and regulations governing their emergency management activities. There was concern voiced that several of CMS' proposals may conflict or overlap with state and local laws and requirements. They recommended that CMS should defer to state and local standards where the proposed CoPs and CfCs would overlap with, be less stringent than, or conflict with those standards.

Response: While we agree that the responsibility for ensuring a community-wide coordinated disaster preparedness response is under the state and local emergency authorities, healthcare facilities will still be required to perform a risk assessment, develop an emergency plan, policies and procedures, communication plan, and train and test all staff to comply with the requirements in this final rule. We disagree that we should defer to state and local standards for emergency preparedness. Also, we do not believe that these requirements will conflict with any state and local standards. These emergency preparedness requirements are the minimal requirements that facilities must meet in order to be in compliance with the emergency preparedness CoPs/CfCs. However, facilities have the option of including as part of their requirements, additional state, local and facility based standards. In particular, the new requirements will require a coordinated and collaborative relationship with state and local governments during a disaster. As such, we agree with the commenters that it is appropriate to add the word "local" in the introductory paragraph for the emergency preparedness requirements. For consistency within the regulation, we will also add the term "local" to the communication plan requirements throughout the regulation.

Comment: Some commenters expressed concern that the term "emergency preparedness program" was discussed in the preamble and then the regulation text used the term "Emergency preparedness plan," and they thought the use of both terms was confusing, a duplication of efforts and a strain on limited resources. Some thought the plan included policies and procedures and training and did not refer to the term "program." Some commenters questioned whether the proposed rule required hospitals to have both an emergency preparedness program and an emergency preparedness plan and questioned if documentation was required for both. They recommended that CMS should clearly stipulate in its standards that only one document is required to demonstrate compliance with the standards.

Some commenters believed that the emergency preparedness policies and procedures based on the emergency plan and risk assessment could be a potential duplication of effort. They recommended that CMS only require healthcare organizations to document how they will meet the emergency preparedness standards in the emergency preparedness plan, and not require separate policies and procedures. They stated that the concept of an emergency preparedness plan is equivalent to a policy, and the emergency preparedness plan states how the hospital will meet a standard.

Response: We agree that the words "program" and "plan" are often used interchangeably. However, in this final rule we use the word "program" to describe a facility's comprehensive approach to meeting the health and safety needs of their patient population during an emergency. We use the word "plan" to describe the individual components of the program such as an emergency plan, policies and procedures, a communication plan, testing and training plans. Regardless of the various synonyms for the words "program" or "plan", we expect a facility to have a comprehensive emergency preparedness program that addresses all of the required elements. An emergency program could be implemented if an internal emergency occurred, such as a flood or fire in the facility, or if a community emergency occurred, such as a tornado, hurricane or earthquake. However, for the purpose of this rule, an emergency or a disaster is defined as an event that affects the facility or overall target population or the community at large or precipitates the declaration of a state of emergency at a local, state, regional, or national level by an authorized public official such as a Governor, the Secretary of the Department of Health and Human Services (DHHS), or the President of the United States.

An emergency plan is one part of a facility's emergency preparedness program. The plan provides the framework, which includes conducting facility-based and community-based risk assessments that will assist a facility in addressing the needs of their patient populations, along with identifying the continuity of business operations which will provide support during an actual emergency. In addition, the emergency plan supports, guides, and ensures a facility's ability to collaborate with local emergency preparedness officials. As a separate standard, facilities will be required to develop policies and procedures to operationalize their emergency plan. Such policies and procedures should include more detailed guidance on what their staff will need to develop and operationalize in order to support the services that are necessary during an actual emergency.

Comment: Some commenters stated that the requirement to update the policies and procedures annually was excessive. Some suggested review only as needed, and several thought this requirement was burdensome. Some commenters suggested that the plan should only be reviewed after an emergency event occurred. A few suggested that only the necessary administrative personnel would need to review the plan according to their policy. Some commenters suggested that weather-related emergencies be reviewed and updated seasonally or quarterly.

Response: We disagree that an annual update is excessive or overly burdensome. We believe it is good business practice to review and evaluate at least annually for revisions that will improve the care of patients, staff and local communities. It is important to keep facility staff updated and trained, as evidenced by policy and procedural updates often occurring not only as a result of an emergency that the facility experienced, but as has been noted in the local and international news. For example, there are various infections and diseases, such as the Ebola outbreak in October, 2014, that required updates in facility assessments, policies and procedures and training of staff beyond the directly affected hospitals. The final rule requires that if a facility experiences an emergency, an analysis of the response and any revisions to the emergency plan will be made and gaps and areas for improvement should be addressed in their plans to improve the response to similar challenges for any future emergencies.

Comment: Some commenters viewed the organization of the emergency plan in the proposed rule as separate from the emergency preparedness policies and procedures. Some hospitals have an emergency plan that consists of emergency policies and procedures in a single document that is updated periodically. They recommended that CMS recognize that the plan may represent the policies and procedures.

Response: The format of the emergency preparedness plan and emergency policies and procedures that a hospital or facility uses are at their discretion. However, it must include all the requirements included for the emergency plan and for the policies and procedures.

Comment: A commenter questioned why mitigation was not included in the risk assessment process as part of the evaluation in reviewing the strategies used during an emergency as related to possible future similar events. The commenter noted that FEMA provides resources, including grant programs, for mitigation planning for communities. According to FEMA documents, assistance from local emergency management officials is available in identifying hazards in their community, and recommending options to address them. A few commenters recommended that we modify the regulation to include mitigation.

Response: We understand the commenters' concerns, however our new emergency preparedness requirements focus on continuity of operations, not hazard mitigation, which refers to actions to reduce to eliminate long term risk to people and property from natural disasters. The emergency plan requires facilities to include strategies for addressing the identified emergency events that have been developed from the facility and the community-based risk assessments. These strategies include addressing changes that have resulted from evaluating their risk assessment process. We decided to not include specific mitigation requirements as part of the emergency plan and instead, base the plan on using an all-hazards approach which can include mitigation activities to lessen the severity and impact a potential disaster or emergency can have on a health facility's operation. Facilities can choose to include hazard mitigation strategies in their emergency preparedness plan. However, we have not made hazard mitigation a requirement. We refer commenters that are interested in hazard mitigation to the following resources for more information:

- *National Mitigation Framework: http://www.fema.gov/national-mitigation-framework.*
- *FEMA Hazard Mitigation Planning: http://www.fema.gov/hazard-mitigation-planning.*

Comment: Commenters agreed that a hospital should evaluate both community-based and facility-based risks but did not believe that CMS provided enough clarity about which entity is expected to conduct the community-based risk assessment. It is unclear whether CMS would expect a hospital to conduct its own assessment outside of the hospital or rely on an assessment developed by entities, such as regional healthcare coalitions, public health agencies, or local emergency management. The commenters suggested that CMS allow hospitals to develop a hazard vulnerability risk assessment by a different organization if deemed adequate or conduct their own assessment with input from key organizations as is consistent with TJC and NFPA® standards.

Response: We agree that a hospital could rely on a community-based assessment developed by other entities, such as their public health agencies, emergency management agencies, and regional healthcare coalitions or in conjunction with conducting its own facility-based assessment. We would expect the hospital to have a copy of this risk assessment and to work with the entity that developed it to ensure that the hospital emergency plan is in alignment.

Comment: Some commenters questioned if the proposed rule would allow an aggregation of risk assessments for multiple sites.

Response: As discussed previously, we are allowing integrated plans for integrated health systems. Please refer to the "Integrated health Systems" section of this final rule for further information.

Comment: Some commenters thought "The National Planning Scenarios" discussed in the proposed rule were a good tool, but the risk assessment developed at the organizational level should be the driving force behind the emergency plan. It was recommended that we clarify that the scenarios are merely variables that could be considered in addition to the organization's risk assessment of potential local threats.

Response: We agree with the commenters. In accordance with § 482.15(a)(1), the hospital must develop an emergency plan based on a risk assessment. As stated in the proposed rule, The National Planning Scenarios were suggested as a possible tool that facilities could consider in the development of their emergency plan along with the development of the facility and community risk assessments.

Comment: Some commenters believed the examples listed in the preamble addressing patient populations, including persons at-risk, were not comprehensive enough and requested that more categories be included. Some stated that a "patient population" included *all* patients; otherwise, they would not be in a facility receiving treatment or care. The commenters suggested that at-risk populations (geriatric, pediatric, disabled, serious chronic conditions, addictions, or mental health issues) served in all provider settings receive similar emphasis in guidance. A commenter stated that the at-risk definition should be limited to those persons who are identified by statute or who are assessed by the provider as being vulnerable due to physical and cognitive functioning impairments. Some commenters were concerned that the wording of the regulation could create the expectation that hospitals would be required to care for all individuals in the community who had additional needs. They believed community-wide planning should ensure that alternate locations be established for such things as individuals dependent on medical equipment that requires electricity for recharging their equipment. Some commenters suggested adding language "of providing acute medical care and treatment in an emergency to describe the services that they will have the ability to provide to their patient population."

Response: In the proposed rule, several types of patient populations were described as at-risk. More examples would have required an exhaustive list and even then, not all categories would have been included. Other suggested categories, as set out in the comment, could be included in the individual facility's assessments and would not be limited to the examples listed in the proposed rule.

As is often the case, in times of emergency, people seek assistance at general hospitals for such things as charging batteries for their medical equipment, and obtaining medical supplies such as oxygen, which they need for their care. The commenters' suggestion that community-wide alternate locations be established to handle these needs would need to be arranged with their local emergency preparedness officials. To facilitate that, the proposed rule requires a process for ensuring cooperation and collaboration with local, tribal, regional, state, and federal emergency preparedness officials in order to ensure an integrated response during a disaster or emergency situation. Facilities are encouraged to participate in a local healthcare coalition as it may provide assistance in planning and addressing broader community needs that may also be supported by local health department and emergency management resources. Facilities may include establishing community-wide alternate locations in their facility plan. Individual facilities would not be expected to take care of all the needs in the community during an emergency.

Comment: Several commenters stated that we did not require facilities to evaluate strategies for addressing surge capacity within the initial risk assessment. They suggested that we require facilities to address surge capacity in their emergency plans. Another commenter stated that facilities should develop specialized plans to address the needs of their patients with disabilities or who are medically dependent (for example, patients requiring dialysis or ventilator).

Response: We believe that an emergency preparedness plan based on an all-hazards risk assessment would include plans for the potential of surge activities during an emergency. The emergency plan should also consider the needs of the entire patient and staff populations.

Comment: Commenters requested clarification about what is meant by "type of services" the provider/suppliers have the ability to provide in an emergency.

Response: Based on the emergency situation and the facility's available resources, a facility would need to assess its capabilities and capacities in order to determine the type of care and treatment that could be offered at that time based on its emergency preparedness plan.

Comment: Some facilities questioned how they could include a process for ensuring cooperation and collaboration with local, tribal, regional, state, and federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation. Some commenters stated that they already had this requirement in their states' regulations and were already familiar with the process. Many commenters believed the term "ensuring" was too onerous for providers and suppliers and CMS did not take into consideration that the State and local emergency officials also had responsibilities. A commenter suggested adding language: "with the goal of implementing an integrated response during a disaster or emergency situation, including documentation of the hospital's efforts to contact such officials and when applicable, its participation in collaborative and cooperative planning efforts." Several commenters recommended replacing the word "ensure" with the words "strive for." Some believed this requirement was important but with limited funds available, implementation would be excessively burdensome.

Response: As noted previously, some commenters stated that they were already familiar with the process for ensuring cooperation and collaboration with various levels of emergency preparedness officials. Providers and suppliers must document efforts made by the facility to cooperate and collaborate with emergency preparedness officials. While we are aware that the responsibility for ensuring a coordinated disaster preparedness response lies upon the state and local emergency planning authorities, we have stated previously in this rule that providers and suppliers must document efforts made by the facility to cooperate and collaborate with emergency preparedness officials. Since some aspects of collaborating with various levels of government entities may be beyond the control of the provider/supplier, we have stated that these facilities must include in their emergency plan a process for cooperation and collaboration with local, tribal, regional, state, and federal emergency preparedness officials.

Comment: A commenter suggested that CMS take into account potential language barriers that may occur in rural areas during an emergency. The commenters recommended that CMS include a requirement for a formal interpreter to interact with non-English speaking patients during an emergency.

Response: Facilities are required to have an emergency preparedness plan that addresses the usual patient population of the community the hospital serves. In addition, certified Medicare providers and suppliers are required to provide meaningful access to Limited English Proficient (LEP) persons under the provider agreement and supplier approval requirement (§ 489.10), to comply with Title VI of the Civil Rights Act of 1964. Title VI requires Medicare participants to take reasonable steps to ensure meaningful access to their programs and activities by LEP persons.

Comment: A commenter stated that the risk assessment should include the availability of emergency power or a plan for ensuring emergency power with the owner of a building in which the facility operates when a facility is not owned by the provider.

Response: It is the responsibility of the healthcare provider that is renting a facility to discuss issues of ensuring that they can continue to provide healthcare during an emergency if the structure of the building and its utilities are impacted. We would expect providers to include this in their risk assessment. As discussed in the next section, we require facilities to develop policies and procedures to address alternate sources of energy.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- Revising the introductory text of § 482.15 by adding the term "local" to clarify that hospitals must also coordinate with local emergency preparedness systems.
- Revising § 482.15(a)(4) to remove the word "ensuring" and replacing the word "ensure" with "maintain."

2. Policies and Procedures (§ 482.15(b))

We proposed at § 482.15(b) that a hospital be required to develop and implement emergency preparedness policies and procedures based on the emergency plan proposed at § 482.15(a), the risk assessment proposed at § 482.15(a)(1), and the communication plan proposed at § 482.15(c). We proposed that these policies and procedures be reviewed and updated at least annually.

We proposed at § 482.15(b)(1) that a hospital's policies and procedures would have to address the provision of subsistence needs for staff and patients, whether they evacuated or sheltered in place, including, but not limited to, at § 482.15(b)(1)(i), food, water, and medical supplies. We noted that the analysis of the disaster caused by the hurricanes in the Gulf States in 2005 revealed that hospitals were forced to meet basic subsistence needs for community evacuees, including visitors and volunteers who sheltered in place, resulting in the rapid depletion of subsistence items and considerable difficulty in meeting the subsistence needs of patients and staff. Therefore, we proposed that a hospital's policies and procedures also address how the subsistence needs of patients and staff that were evacuated would be met during an emergency.

At § 482.15(b)(1)(ii) we proposed that the hospital have policies and procedures that address the provision of alternate sources of energy to maintain: (1) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions; (2) emergency lighting; and (3) fire detection, extinguishing, and alarm systems. At § 482.15(b)(1)(ii)(D), we proposed that the hospital develop policies and procedures to address the provisions of sewage and waste disposal including solid waste, recyclables, chemical, biomedical waste, and waste water.

At § 482.15(b)(2), we proposed that the hospital develop policies and procedures regarding a system to track the location of staff and patients in the hospital's care, both during and after an emergency. We stated that it is imperative that the hospital be able to track a patient's whereabouts, to ensure adequate sharing of patient information with other facilities and to inform a patient's relatives and friends of the patient's location within the hospital, whether the patient has been transferred to another facility, or what is planned in respect to such actions. We did not propose a requirement for a specific type of tracking system. We believed that a hospital should have the flexibility to determine how best to track patients and staff, whether it uses an electronic database, hard copy documentation, or some other method. However, we stated that it is important that the information be readily available, accurate, and shareable among officials within and across the emergency response system, as needed, in the interest of the patient and included in their policies and procedures.

We proposed at § 482.15(b)(3) that a hospital have policies and procedures in place to ensure safe evacuation from the hospital, which would include consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance. We proposed at § 482.15(b)(4) that a hospital have policies and procedures to address a means to shelter in place for patients, staff, and volunteers who remain in the facility. We indicated that we would expect that hospitals include in their policies and procedures both the criteria for selecting patients and staff that would be sheltered in place and a description of how they would ensure their safety.

We proposed at § 482.15(b)(5) that a hospital have policies and procedures that would require a system of medical documentation that would preserve patient information, protect the confidentiality of patient information, and ensure that patient records are secure and readily available during an emergency. In addition to the current hospital requirements for medical records located at § 482.24(b), we proposed that hospitals be required to ensure that patient records are secure and readily available during an emergency. We indicated that such policies and procedures would have to be in compliance with Health Insurance Portability and Accountability Act (HIPAA) Rules at 45 CFR parts 160 and 164, which protect the privacy and security of an individual's protected health information. We proposed at § 482.15(b)(6) that facilities have policies and procedures in place to address the use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of state or federally designated healthcare professionals to address surge needs during an emergency.

We proposed at § 482.15(b)(7) that hospitals have a process for the development of arrangements with other hospitals and other facilities to receive patients in the event of limitations or cessation of operations at their facilities, to ensure the continuity of services to hospital patients. This requirement would apply only to facilities that provide continuous care and services for individual patients; therefore, we did not propose this requirement for transplant centers, CORFs, OPOs, clinics, rehabilitation agencies, and public health agencies that provide outpatient physical therapy and speech-language pathology services, or RHCs/FQHCs.

We also proposed at § 482.15(b)(8) that hospital policies and procedures would have to address the role of the hospital under a waiver declared by the Secretary, in accordance with section 1135 of the Act, for the provision of care and treatment at an alternate care site identified by emergency management officials. We proposed this requirement for inpatient providers only. We stated that we would expect that state or local emergency management officials might designate such alternate sites, and would plan jointly with local facilities on issues related to staffing, equipment and supplies at such alternate sites. This requirement encourages providers to collaborate with their local emergency officials in proactive planning to allow an organized and systematic response to assure continuity of care even when services at their facilities have been severely disrupted. Under section 1135 of the Act, the Secretary is authorized to temporarily waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements for healthcare providers to ensure that sufficient healthcare items and services are available to meet the needs of individuals enrolled in these programs in an emergency area (or portion of such an area) during any portion of an emergency period. Under an 1135 waiver, healthcare providers unable to comply with one or more waiver-eligible requirements may be reimbursed and exempted from sanctions (absent any determination of fraud or abuse). Additional information regarding the 1135 waiver process is provided in the CMS Survey and Certification document entitled, "Requesting an 1135 Waiver", located at: *http://www.cms.gov/About-CMS/Agency-Information/H1N1/downloads/requestingawaiver101.pdf.*

Comment: A commenter stated that we should clarify that if a hospital is destroyed in an emergency but personnel are present with the relevant expertise, then personnel may function within their scope of practice in a makeshift location.

Response: We agree that if a hospital is destroyed in an emergency, the medical personnel of that hospital should be able to function within their scope of practice in an alternate care site to provide valuable medical care. The hospital and other inpatient providers should address this issue in their policies and procedures. These providers, in accordance with section 1135 of the Act, should have policies and procedures for the provision of care and treatment at an alternate care site identified by emergency management officials. We would expect that state or local emergency management officials would plan jointly with local facilities on issues related to staffing, equipment and supplies at such alternate sites.

The comments we received on our proposed requirement for hospitals to develop and implement emergency preparedness policies and procedures are discussed later in this final rule. We also proposed that all providers and suppliers review and update their policies and procedures at least annually. We received a few comments on this issue.

Comment: A few commenters indicated that a requirement for annual updates to the policies and procedures is the most feasible for facilities. A commenter stated that annual updates are not only reasonable, but also necessary in order to ensure that emergency plans and procedures are adequate and current. Other commenters stated that a stricter requirement, for example of bi-annual updates, would be burdensome and unrealistic for facilities to meet. Still other commenters stated that the requirement to update policies and procedures annually was excessive and burdensome. Some suggested review on an "as needed" basis instead. Some suggested that weather-related emergencies be reviewed and updated seasonally or quarterly.

Response: We appreciate the feedback from commenters and we agree that requiring annual updates is effective and the most realistic expectation of facilities. We do not agree that an annual update is excessive or overly burdensome. It is important to keep facility staff updated and trained on emergency policies and procedures regardless of whether the facility has experienced an actual emergency. For example, various infections and diseases, such as the Ebola outbreak in October 2014, have required updates in facility assessments, policies and procedures, and training of staff to ensure the health and safety of their patients and employees. Facilities are free to update as needed but at least annually.

Comment: Most commenters believed that providing for the subsistence needs of patients and staff was appropriate but only if sheltering in place. If patients were evacuated, the receiving facility should be responsible for those needs. Some commenters believed that community organizations, and local emergency management agencies should provide for subsistence needs when patients are sent to the receiving facilities. Some commenters questioned other agencies'/organizations' requirements and how that would impact their current requirements; some questioned whether certain amounts were sufficient and many were concerned about the burden with many facilities operating on limited budgets. Other commenters suggested we should require facilities to have a minimum store of provisions to meet the needs of their patient or resident populations for 72 to 96 hours. The commenters stated that we should clarify the amount of time to provide subsistence during and after an emergency. Other commenters stated that we should not mandate specific subsistence needs and quantities and a few commenters stated that we should delete the requirement for a hospital to provide subsistence in the event of an evacuation.

Response: We would first like to point out that we are requiring certain facilities to have policies and procedures to address the provision of subsistence in the event of an emergency. This does not mean that facilities would need to store provisions themselves. We agree that once patients have been evacuated to other facilities, it would be the responsibility of the receiving facility to provide for the patients' subsistence needs. Local, state and regional agencies and organizations often participate with facilities in addressing subsistence needs, emergency shelter, etc. Secondly, we are not specifying the amount of subsistence that must be provided as we believe that such a requirement would be overly prescriptive. Facilities can best manage this based on their own facility risk assessments. We disagree with setting a rigid amount of subsistence to have on hand at any given time in the event of an emergency. Based on our experience with inpatient healthcare facilities to allow each facility the flexibility to identify the subsistence needs that would be required during an emergency, mostly likely based on level of impact, is the most effective way to address subsistence needs without imposing undue burden.

Comment: In response to a solicitation of public comments in the proposed rule, almost all the facility commenters stated that they did not see subsistence preparations for individuals residing in the larger community as their responsibility. The commenters stated that local and state emergency management personnel along with civic organizations such as the Red Cross should be responsible for meeting these needs. In addition, the cost for the facilities to provide these services to the community would be unsustainable. Some commenters interpreted the proposed regulation text to not only include responsibility for patients and staff in the facility, but also individuals in the community.

Response: We agree with the commenters and did not mean to suggest that facilities are also responsible for individuals in the community. While we believe it would be a good practice to prepare for these "community individuals," we are not requiring it under § 482.15(b)(1). The provision on subsistence needs applies only for staff and patients.

Comment: Commenters suggested that we add "pharmaceuticals or medications" to provisions of food, water and medical supplies.

Response: We agree with the commenters' suggestion and have added pharmaceuticals to the list of subsistence needs in the regulation text.

Comment: A commenter questioned why supplies, such as personnel, power, water, and finances, are not addressed in relation to subsistence needs in the proposed rule. The commenter noted that the requirements do not include how these supplies will be sustained during emergency situations.

Response: We have included requirements that facilities develop and maintain emergency preparedness policies and procedures that address subsistence needs for staff and patients at § 482.15(b)(1). However, we believe the rule allows flexibility so that facilities can determine how they will acquire provisions and use them for the needs of patients and staff.

Comment: A commenter stated that we should delete the requirement we proposed at § 482.15(b)(4) that a hospital must have policies and procedures to address a means to shelter in place for patients, staff, and volunteers who remain in the facility. The commenter inquired about what a hospital should do with the patients that they decide are not going to be sheltered in place and rescue crews cannot make it to the hospital to remove them.

Response: Plans should be made to shelter all patients in the event that an evacuation cannot be executed. We state at § 482.15(b)(1) that provisions should be made for patients and staff whether they evacuate or shelter in place. However, with advance notice in event of an emergency, it may be medically necessary for some of the patient population to be evacuated in advance. During an emergency, often the hospital may be the only available resource to patients and are the focal points for healthcare in their respective communities. It is essential that hospitals have the capacity to respond in a timely and appropriate manner in the event of a natural or man-made disaster. Since Medicare participating hospitals are required to evaluate and stabilize every patient seen in the emergency department and to evaluate every inpatient at discharge to determine his or her needs and arrange for post-discharge care as needed, hospitals are in the best position to coordinate emergency preparedness planning with other providers and suppliers in their communities. Relief staff may be unable to get to the hospital thus requiring staff to remain at the hospital for indefinite periods of time. We disagree with removing the requirement for facilities to make the necessary plans to provide food, water, medical supplies, and subsistence needs for the patients, staff, and volunteers who remain in the facility. As we have noted previously, the policy only requires that the hospital have policies to provide for subsistence needs, which we believe are not unduly burdensome. We are not setting minimum requirements or standards for these provisions in hospitals.

Comment: A commenter recommended that we require the electronic monitoring of fire extinguishers. The commenter stated that this requirement would address the widespread non-compliance of fire extinguisher code regulations. Another commenter disagreed with the use of electronic monitoring of fire extinguishers, arguing that retrofitting fire extinguishers with this technology would be costly.

Response: This recommendation is not within the scope of this regulation. For additional information we refer readers to our current Life Safety Code regulations (for hospitals, § 482.41(b)).

Comment: In addition to the general comments discussed earlier that we received regarding our proposal for certain providers and suppliers to track staff and patients during and after an emergency, we also received a few comments specific to the tracking requirement for hospitals. Many questioned the complexity of the tracking documentation and what information would be needed. Some commenters stated that patient tracking within the hospital should be distinguished from tracking patients outside of the hospital, in the hospital's care, or whether they are located at an alternate care site operated by the hospital. Moving and tracking of patients may also be the responsibility of an entity other than the hospital, such as state and emergency management officials and the hospitals may not know the destination of the individuals. Some commenters requested clarification regarding what we mean by a "system to track."

Commenters noted that the facility's tracking system may not be compatible with the hospital's IT system. If the system lacks interoperability, it becomes difficult to share information across the emergency management system.

Commenters suggested that CMS change the current language and instead add "a hospital would be required to have a process to locate staff and track the location of patients in the hospital's care both during and throughout the emergency." Some commenters interpreted the proposed requirement to include the hospital's responsibility of tracking the whereabouts of patients in outpatient facilities (assuming they are part of the hospital). These commenters recommended that CMS remove this requirement.

Response: We appreciate the commenters' feedback and have clarified our expectations. As indicated previously, we have removed "after the emergency" from the regulation text. Furthermore, we are revising the regulation text to clarify that we would expect facilities to track their on-duty staff and sheltered patients during an emergency and document the specific location and name of where a patient is relocated to during an emergency (that is, to another facility, home, or alternate means of shelter, etc.). As we stated in the proposed rule, we did not propose a requirement for a specific type of tracking system. By "system to track" we mean that facilities will have the flexibility to determine how best to track patients and staff, whether they utilize an electronic database, hard copy documentation, or some other method. We would expect that the information would be readily available, accurate, and shareable among officials within and across the emergency response system, as needed, in the interest of the patient.

Comment: Some commenters questioned who would assign evacuation locations outside the facility if it was determined necessary. If internal, they believe the provider or supplier should decide.

Response: Decisions about evacuation locations within a facility should be made by the provider or supplier. If patients must be evacuated outside of the facility, a joint decision could be made by the facility and the local health department and emergency management officials.

Comment: Several commenters stated that the same transportation services may be planned for use by several facilities and that planning should consider multiple options in the event of an evacuation.

Response: We agree with the commenters. We suggest that facilities consider identifying potential redundant transportation options and collaborate with healthcare coalitions to better inform and assist in planning activities for the efficient and effective use of limited resources.

Comment: Some commenters questioned our proposal to shelter volunteers and voiced concern about their legal responsibilities. A commenter stated that it would be challenging for some facilities to provide shelter for patients, staff, and volunteers who remain in the facility. Commenters expressed concern in response to our proposal that hospitals' "shelter-in-place" policies include both the criteria for selecting patients and staff that would be sheltered, and a description of how they would ensure their safety. Some commenters stated that this appeared to lack significant evidence of being an effective policy. The commenters questioned what we expected a hospital to do with the patients that the hospital decides not to shelter in place, if rescue crews could not make it to the hospital to remove them. Other commenters believed hospitals should prepare to shelter in place all patients, staff, and visitors. The commenters recommended that CMS modify its proposal to permit hospitals to decide which patients and staff to shelter.

Response: We agree that sheltering in place can be a challenge to facilities. However, the emergency plan requires strategies for addressing this issue in the facility risk assessment. As such, we disagree with revising our policy for sheltering in place. We require facilities to have a means to shelter in place for patients, staff, and volunteers who remain in the facility. Based on its emergency plan, a hospital could decide to have various approaches to sheltering some or all of its patients, staff and visitors. The plan should take into account the available beds in the area to which patients could be transferred in the event of an emergency. For example, if it is risky or the emergency affects available sites for transfer or discharge, then the patients would remain in the facility until it was safe to transfer or discharge. Also, we would expect providers and suppliers to have policies and guidelines for sheltering volunteers and visitors during an emergency. Facilities must determine their policies based on the emergency and the types of visitors/volunteers that may be present during and after an emergency.

Comment: Some commenters questioned if the system of medical documentation has to be electronic. Some stated that they already have this in place in their facilities. Many stated that electronic health records (EHRs) are not used universally and, if required, would be unrealistic to put into operation for this requirement and would be burdensome to their overall fiscal operation. Many commenters believed multiple IT systems would be incompatible. Some commenters pointed out that if power were lost, they would lose the ability to copy records and use computers to access patient records. Some facility commenters stated that they use paper documents (pre-printed forms) that document relevant patient information and attach them to patients during an evacuation. A commenter believed that some facilities would find it difficult to provide a system of medical documentation that would ensure that medical records were complete, confidential, secure, and readily available. The same commenters stated that it would also be challenging for them to share medical documentation and relevant patient information with other healthcare facilities to ensure continuity of healthcare and treatment during an emergency.

Response: We are not requiring EHRs as part of the medical record documentation requirements. Medicare- and Medicaid-participating facilities are in varying stages of EHR adoption, and therefore, many would be unable to electronically share relevant patient care information with other treating healthcare facilities during an emergency. However, we do expect facilities to be able to provide a means to preserve and protect patient records and ensure that they are secure, in order to provide continuity in the patient's care and treatment. We would expect facilities' plans to address how a provider, in the event of an evacuation, would release patient information, as permitted under 45 CFR 164.510 of the HIPAA Privacy Rule. This section of the HIPAA Privacy Rule sets out "Uses and disclosures requiring an opportunity for the individual to agree or to object." Facilities should establish an effective communication system, in accordance with the HIPAA Privacy Rule, that could generate timely, accurate information that can be disseminated, as permitted, to family members and others. Facilities should also consider including in their communication plan information on what type of patient information is releasable and who is authorized to release this information during an emergency. Additional information and resources regarding the application of the HIPAA Privacy Rule during emergency scenarios can be located at: *http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/emergency/*.

Comment: Some commenters stated that the development of arrangements with hospitals or other providers and suppliers to receive patients in the event of limitation of services, so as to assure continuity of services, was unrealistic, due to limited availability of resources (that is, other hospitals or facilities may be experiencing limitation of services or there are no other providers or suppliers in the area).

Response: We understand that during an emergency other available healthcare resources may be strained, but the development of arrangements in collaboration with other facilities to receive patients is necessary in order to provide the continued needed care and treatment for all patients. If arranged resources are unavailable during an emergency, then the facility should use the available resources in its community. Facilities are encouraged to participate with its local healthcare coalition to gain a broader understanding of other facilities and potential resources, both facility and community, that may be available during an emergency.

Comment: Some commenters stated that any alternate care site should be identified either by the provider or supplier alone or in conjunction with the emergency management officials. A few commenters questioned the legal responsibilities of the staff working at the alternate care site. Some commenters questioned the effect of a waiver on their reimbursement process. Many questions and concerns about staffing responsibilities were related to who would make staffing decisions and who would pay alternate care site salaries. Some commenters stated that the staff could not be spared from their facilities even in emergency circumstances.

Response: Health department and emergency management officials, in collaboration with facility staff, would be responsible for determining the need to establish an alternate care site as part of the delivery of care during an emergency. The alternate care site staff would be expected to function in the capacity of their individual licensure and best practice requirements and laws. Professional staff normally carries malpractice insurance and facilities also have malpractice insurance, which would also include coverage for their employees. Decisions regarding staff responsibilities would be determined based on the facility- and community-based assessments and the type of services staff could provide. This regulation does not address payment issues.

Comment: Many commenters stated that they would be unable to provide or obtain alternative sources of energy during an emergency. They questioned who would decide what are acceptable types of energy sources (such as propane or battery-operated) and what service needs could be met, such as operating rooms, emergency departments, and surgical and intensive care units. Several commenters recommended that CMS state how long a hospital would be expected to provide alternative or backup power.

Response: Alternate sources of energy depend on the resources available to a facility, such as battery-operated lights, propane lights, or heating, in order to meet the needs of a facility during an emergency. We would encourage facilities to confer with local health department and emergency management officials, as well as and healthcare coalitions, to determine the types and duration of energy sources that could be available to assist them in providing care to their patient population during an emergency. As part of the risk assessment planning, facilities should determine the feasibility of relying on these sources and plan accordingly.

Comment: Some commenters stated that alternate sources of energy to maintain temperatures for patient health and safety may not be realistic to achieve because their emergency systems may already have pre-planned areas of need, such as use in the emergency department, operating rooms, intensive care units, and necessary medical life sustaining needs, such as ventilators, oxygen and intravenous equipment, and cardiac monitoring equipment. In clinical care areas of facilities, patients may have to be moved, fans may have to be brought in or temperature control may be outside of the facility's control entirely. Temperatures to maintain safe and sanitary storage of provisions may not be viable due to limited backup power. Commenters recommended that these requirements be aligned with the current NFPA® standards. Commenters recommended that we require hospitals to describe in their emergency plans how they will mitigate specific scenarios, such as if they are unable to maintain temperatures or refrigeration. In addition, they review their current emergency power capacity and assess whether upgrades should be made. The commenters stated that CMS' proposed rule could be interpreted as increasing requirements on electrical systems and require upgrades to those systems, which could be costly to accomplish.

Response: We understand that protocols for emergency distribution of energy within a facility may have already been set to accommodate such priorities as emergency lighting, fire detection, alarm systems, and providing life-sustaining care and treatment. We agree with the commenters that facilities should include as part of their risk assessment how specific needs will be met to maintain temperatures to protect patient health and safety. We are not requiring facilities to upgrade their electrical systems, but after their review of their facility risk assessment, facilities may find it prudent to make any necessary adjustments to ensure that patients' health and safety needs are met and that facilities maintain safe and sanitary storage areas for provisions.

Comment: Many commenters expressed concern about their perception that they would be held responsible for maintaining sewage and waste disposal in their facility during and after an emergency event. The commenters thought that such matters were outside their scope of responsibilities. Some thought our expectations were unclear. Some commenters noted that energy is not always required for these processes. A commenter stated that in some emergencies, infrastructure could be damaged, backup power could be unavailable, local water and sewage services could be limited or unavailable, or their hazardous waste disposal contractors could be unavailable. Other commenters recommended that CMS require hospitals to have backup plans if their primary waste-handling operations become disabled or disrupted, which could include storing waste in a secure area until the facility arranged removal. The commenters also recommended that hospitals identify and assess the risks in their risk assessments relating to their facility's wastewater system and describe in their emergency plan how they would address specific scenarios in which sewage might become a problem. Several commenters stated that the treatment of sanitary sewage on site would possibly require the installation of an onsite sewage treatment plant if the municipal system were disrupted, which would be impossible for inner city facilities due to limited physical space. Commenters stated that the proposed rule seemed to require that waste continue to be disposed of in a disaster, and that the proposed rule was too broad.

Response: We agree with the commenters' recommendation that facilities should identify and assess their sewage and wastewater systems as part of their facility-based risk assessment and make necessary plans to maintain these services. We are not requiring onsite treatment of sewage but that facilities make provisions for maintaining necessary services.

Comment: A commenter stated that CMS should revise the requirement at § 482.15(b)(6) to state "use of health care volunteers" to clarify that this requirement is different from the requirement for the use of "general" volunteers.

Response: The intent of this requirement is to address any volunteers. We believe that in an emergency a facility or community would need to accept volunteer support from individuals with varying levels of skills and training and that policies and procedures should be in place to facility this support. Health care volunteers would be allowed to perform services within their scope of practice and training and non-medical volunteers would perform non-medical tasks. As such, we disagree with limiting this requirement to just medical volunteers.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- Revising § 482.15(b)(1)(i) to add that hospitals must have policies and procedures that address the need to stock pharmaceuticals during an emergency.
- Revising § 482.15(b)(2) to remove the requirement for hospitals to track staff and patients after an emergency and clarifying that in the event staff and patients are relocated, hospitals must document the specific name and location of the receiving facility or other location for sheltered patients and on-duty staff who leave the facility during the emergency.
- Revising § 482.15(b)(5) to change the phrase "ensures records are secure and readily available" to "secures and maintain availability of records."
- Revising § 482.15(b)(5) and (7) to remove the word "ensure."
- Adding a new § 482.15(f) to allow a separately certified hospital within a healthcare system to elect to be a part of the healthcare system's emergency preparedness program.

3. Communication Plan (§ 482.15(c))

An effective and well maintained communication plan will facilitate coordinated patient care across healthcare providers, and with state and local public health departments and emergency systems to protect patient health and safety in the event of a disaster. For a hospital to operate effectively in an emergency situation, we proposed at § 482.15(c) that hospitals be required to develop and maintain an emergency preparedness communication plan that complies with both federal and state law. We proposed that hospitals be required to review and update the communication plan at least annually. During an emergency, it is critical that hospitals, and all providers/suppliers, have a system to contact appropriate staff, patients' treating physicians, and other necessary persons in a timely manner to ensure continuation of patient care functions throughout the hospital and to ensure that these functions are carried out in a safe and effective manner. Updating the plan annually would facilitate effective communication during an emergency. Providers and suppliers are to have contact information for federal, state, tribal, regional, or local emergency preparedness staff and other sources of assistance. Patient care must be well coordinated across healthcare providers, and with state and local public health departments and emergency systems to protect patient health and safety in the event of a disaster.

At § 482.15(c)(1), we proposed that the communication plan include names and contact information about staff, entities providing services under arrangement, patients' physicians, other hospitals, and volunteers. We stated that, during an emergency, it is critical that hospitals have a system to contact appropriate staff, patients' treating physicians, and other necessary persons in a timely manner to ensure continuation of patient care functions throughout the hospital and to ensure that these functions are carried out in a safe and effective manner. We proposed at § 482.15(c)(2) to require hospitals to have contact information for federal, state, tribal, regional, or local emergency preparedness staff and other sources of assistance.

We proposed at § 482.15(c)(3) to require that hospitals have primary and alternate means for communicating with the hospital's staff and federal, state, tribal, regional, or local emergency management agencies.

We also proposed at § 482.15(c)(4) to require that hospitals have a method for sharing information and medical documentation for patients under the hospital's care, as necessary, with other healthcare facilities to ensure continuity of care.

We proposed at § 482.15(c)(5) that hospitals have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510 of the HIPAA Privacy Rule. Thus, hospitals would need to have a communication system in place capable of generating timely, accurate information that could be disseminated, as permitted, to family members and others. We believe this requirement would best be applied only to facilities that provide continuous care to patients, as well as to those facilities that take responsibility for and have oversight over or both, care of patients who are homebound or receiving services at home.

We proposed at § 482.15(c)(6) to require hospitals to have a means of providing information about the general condition and location of patients under the facility's care, as permitted under 45 CFR 164.510(b)(4) of the HIPAA Privacy Rule. Section 164.510(b)(4), "Use and disclosures for disaster relief purposes," establishes requirements for disclosing patient information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts for purposes of notifying family members, personal representatives, or certain others of the patient's location or general condition. We did not propose prescriptive requirements for how a hospital would comply with this requirement. Instead, we stated that we would allow hospitals the flexibility to develop and maintain their own system. Lastly, we proposed at § 482.15(c)(7) that a hospital have a means of providing information about the hospital's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

Comment: Many commenters expressed support for the proposal to require hospitals to develop and maintain an emergency preparedness communication plan that complies with both federal and state law and is reviewed and updated annually. A commenter noted that the proposed requirements are consistent with TJC standards. The commenter noted that while they believe that these requirements can be met by larger institutions with ease, smaller institutions may have more difficulties.

A few commenters disagreed with the proposal to require that communications plans have contact information for all staff physicians, families, patients, and contractors. A commenter stated that this would require an additional full time equivalent (FTE) staff member. Another commenter stated that it would be challenging and overly burdensome to maintain a current contact list, especially for volunteers.

A commenter stated that it could be difficult for children's hospitals to maintain a comprehensive list of people and entities, as required for a hospital's communication plan. The commenter gave an example of a hospital that maintains a listing for most managers and above, but not for all general staff and volunteers.

Response: We appreciate the commenters' support and feedback. We disagree with the commenters who suggested that it would be overly burdensome for hospitals to maintain a current contact list. As a best practice, most hospitals maintain an up-to-date list of their current staff for staffing directories and human resource management. In addition, most hospitals have procedures or systems in place to handle their roster of volunteers. We believe that a hospital would have a comprehensive list of their staff, given that these lists are necessary to maintain operations and formulate a payroll. In addition, we continue to believe that it is critically important that hospitals have a way to contact appropriate physicians treating patients, and entities providing services under arrangement, other hospitals, and volunteers during an emergency or disaster event to ensure continuation of patient care functions throughout the hospital and to ensure continuity of care.

Furthermore, we clarify that we are not requiring hospitals to include in their communication plan contact information for the families of staff, or the families of patients who are not directly involved in the patient's care, or contractors not currently providing services under arrangement.

Comment: A commenter recommended that CMS scale back the requirement for an alternate means of communication, in order to allow facilities more time to evaluate existing communications technology and to gradually build toward a more integrated and collaborative system as resources allow.

Response: We do not believe that scaling back the requirements for an alternate means of communication to be used during an emergency would be beneficial to hospitals and their patients. As we have learned over the years, landline telephones are often inoperable for an extended period of time during and after disasters. Cell phones also can be unreliable and are often without reception during an emergency event, or are completely unusable due to a lack of cellular coverage in certain remote and rural areas. Therefore, it is appropriate and vitally important for hospitals to have some alternate means to communicate with their staff and federal, state and local emergency management agencies during an emergency. While we are not endorsing a specific alternate communication system or requiring the use of certain specific devices, we expect that facilities would consider using the following devices:

- Pagers.
- Internet provided by satellite or non-telephone cable systems.
- Cellular telephones (where appropriate). Facilities can also carry accounts with multiple cell phone carriers to mitigate communication failures during an emergency.
- Radio transceivers (walkie-talkies).
- Various other radio devices such as the NOAA Weather Radio and Amateur Radio Operators' (ham) systems.
- Satellite telephone communication system.

Comment: A few commenters expressed support for the proposed language that requires that the hospital's communication plan include a method for sharing information and medical documentation for patients under the hospital's care, as necessary, with other healthcare facilities to ensure continuity of care. The commenters noted that the proposed language is flexible and does not require the use of any specific technology. The commenters recommended that CMS continue to use flexible language in the final rule and not require hospitals to use any specific technology. The commenters noted that, in many instances, hospitals would share information through paper-based documentation.

Response: We appreciate the commenters' support. We reiterate that § 482.15(c)(4) requires that facilities have a method for sharing information and medical documentation for patients under the hospital's care, as necessary, with other healthcare facilities to ensure continuity of care. As the commenters pointed out, we are not requiring, nor are we endorsing, a specific digital storage or dissemination technology. Furthermore, we note that we are not requiring facilities to use EHRs or other methods of electronic storage and dissemination. In this regard, we acknowledge that many facilities are still using paper-based documentation. However, we encourage all facilities to investigate secure ways to store and disseminate medical documentation during an emergency to ensure continuity of care.

Comment: A few commenters objected to the requirement that hospitals have a method for sharing information and medical documentation for patients under the hospital's care. A commenter specifically objected to the sharing of medical records with other health systems. The commenter stated that it is difficult to share this information with facilities that have different systems. Another commenter stated that the expectation that hospitals will share clinical documentation is unrealistic. The commenter noted that many HHAs still operate with paper documentation, are stand-alone facilities, and do not coordinate with other healthcare systems or with other local facilities. The commenter stated that surveyors should be aware that the capability of facilities to communicate patient-specific clinical documentation to other facilities in the local healthcare system is likely to be limited.

Response: We disagree with the commenters' statement that hospitals should not or cannot have a method for sharing information and medical documentation for patients during an emergency or disaster, as necessary. We believe that hospitals should have an established system of communication that would ensure that patient care information could be disseminated to other providers and suppliers in a timely manner, as needed, during an emergency or disaster.

We have seen the importance of formulating this type of communication plan in the past to ensure continuity of care. Sharing patient information and documentation was found to be a significant problem during the 2005 hurricanes and flooding in the Gulf Coast states. In 2011, the ability to share information during the Joplin, Missouri tornado both electronically and via hard copy helped patient evacuations and continuity of care. In addition, during Hurricane Sandy in 2012, some hospitals reported receiving evacuated patients from a nearby hospital with little or no medical documentation (HHS OIG, Hospital Emergency Preparedness and Response During Super Storm Sandy. September 2014). In some cases, electronic medical records were unavailable and only oral patient histories could be provided. This lapse in medical documentation is detrimental to patient care. Therefore, we continue to believe that hospitals should include in their communication plan a method for sharing information and medical documentation for patients under the hospital's care, as necessary, with other healthcare providers to ensure continuity of care. We encourage hospitals and other providers and suppliers to engage in coalitions in their area for assistance in effectively meeting this requirement.

We clarify that we are not requiring the use of EHRs within this regulation and we understand that some hospitals and other providers and suppliers may still be using paper medical records. However, we encourage these facilities to consider the use of alternative means of storing patient care information, to ensure that medical documentation is preserved and easily disseminated during an emergency or disaster.

Comment: A commenter recommended that the requirements pertaining to a method or means of sharing information include timelines for submission of such documentation to other healthcare providers or other entities as described in proposed § 482.15(c)(4) through (6).

Response: We do not believe that it is appropriate to include suggested timelines for facilities to share information and medical documentation for patients under the hospital's care in these emergency preparedness requirements. Instead, we believe that the facility should determine the appropriate timeline for the dissemination of information to other providers and pertinent entities. We have included the language "as necessary" in the regulations to allow facilities flexibility to share information and medical documents as needed to ensure continuity of care for patients during an emergency.

Comment: A few commenters expressed concern about the language used in the preamble, which states that hospitals would share comprehensive patient care information. The commenters noted that the term "comprehensive information" is not defined and suggested that CMS focus on relevant information that enables a care provider to determine what medical services and treatments are appropriate for each patient.

Response: We agree with the commenters that facilities should share relevant patient information to ensure continuity of care for a patient in situations where a provider must evacuate. In addition, we note that while we did not propose to require that providers share comprehensive patient care information, we believe that relevant patient information includes, but is not limited to, the patient's presence or location in the hospital; personal information the hospital has collected on the patient for billing or demographic analysis purposes, such as name, age, address, and income; or information on the patient's medical condition. Although we have not specified requirements for timelines for delivering patient care information, we would expect that facilities would provide patient care information to receiving facilities during an evacuation, within a timeframe that allows for effective patient treatment and continuity of care.

Comment: A commenter requested clarification on the proposal that requires hospital communication plans to include a means, in the event of an evacuation, to release patient information as permitted under current law.

Response: In response to this public comment, we are clarifying that § 482.12 (c)(5) requires that the hospital must have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii), which establishes permitted uses and disclosures of protected health information to notify a family member, a personal representative of the individual, or another person responsible for the individual's location, general condition, or death. We are also clarifying in parallel provisions of the regulation that RNHCIs, ASCs, hospices, PRTFs, PACE organizations, LTC facilities, ICF/IID facilities, CAHs, CMHCs, and dialysis facilities must have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

Facilities should establish an effective communication system, in accordance with the previously referenced provision of the HIPAA Privacy Rule that could generate timely, accurate information that can be disseminated, as permitted, to family members and others. Facilities should also consider including in their communication plan information on what type of patient information is releasable and who is authorized to release this information during an emergency.

Comment: A commenter expressed concern over the financial burden that smaller institutions may incur when implementing a system for sharing information. The commenter noted that this burden may be reduced as more institutions move towards EHRs. Therefore, the commenter recommended a phased-in approach to implementing this requirement.

Response: We understand the commenter's concern about the potential financial burden that smaller facilities may incur. However, we have not specified a method or a system for sharing patient information. These regulations enable facilities to develop procedures that best meet their needs and take into account their facility's resources. Additionally, we believe that many facilities already have basic emergency preparedness plans, which may reduce the cost of implementation.

We encourage facilities to engage in healthcare coalitions in their area for assistance. We also refer facilities to the following Web sites for more information about emergency communication planning:

- *http://transition.fcc.gov/pshs/emergency-information/guidelines/health-care.html*
- *http://www.dhs.gov/government-emergency-telecommunications-service-gets*
- *http://www.phe.gov/preparedness/planning/hpp/reports/documents/capabilities.pdf*

Comment: Several commenters expressed concern about the proposed provisions that would require hospitals to include a means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4). Commenters noted that hospitals should already have HIPAA compliance plans in place that would address emergency situations. They also noted that some states have stricter privacy laws than HIPAA and, therefore, the commenters recommended that the regulatory language include a phrase that states that facilities should comply with applicable state privacy laws in addition to HIPAA.

A few commenters questioned if the HIPAA privacy laws would be relaxed or waived during an emergency. A commenter requested clarification on privacy rules in emergency situations across all providers and suppliers, first responders, and community aid organizations.

Response: Section 482.15(c) states that hospitals must develop and maintain an emergency preparedness communication plan that complies with both federal and state law. This phrase is applicable to the requirement that hospitals should provide a means of providing information about the general condition and location of patients under the facility's care; therefore, hospitals are required to comply with both 45 CFR 164.510(b)(4) and all pertinent state laws. Several commenters recommended that the regulatory language include a phrase that states that facilities should comply with applicable state privacy laws in addition to HIPAA. We note that the requirement as currently written will require hospitals to comply with all pertinent state laws, including pertinent state privacy laws, and that it is not necessary to add additional language.

HIPAA requirements are not suspended during a national or public health emergency. However, the HIPAA Privacy Rule specifically permits certain uses and disclosures of protected health information in emergency circumstances and for disaster relief purposes, as described in HHS guidance at *http://www.hhs.gov/hipaa/for-*

professionals/special-topics/emergency-preparedness/index.html. In addition, under section 9 of the Project Bioshield Act of 2004 (Pub. L. 108–276), which added paragraph 1135(b)(7) to the Act, the Secretary of HHS may waive penalties and sanctions against facilities that do not comply with certain provisions of the HIPAA Privacy Rule if the President declares an emergency or a disaster and the Secretary declares a public health emergency.

Facilities and their legal counsel should review the HIPAA Privacy Rule carefully before deciding to share patient information. We refer readers to the following resources for more information on the application of the HIPAA Privacy Rule during an emergency:

- *http://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/*
- *http://www.hhs.gov/sites/default/files/emergencysituations.pdf*
- *http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/emergency/index.html*

Comment: A few commenters stated that the language set out in the proposed rule describing requirements for a hospital's communication plan would have broad implications for EHRs. The commenters noted that this regulation could result in facilities being deemed non-compliant for reasons outside of their control, since, as they argue, the industry does not have the ability to electronically transfer or share patient information and medical documentation in a disaster with other healthcare facilities in a HIPAA-compliant manner.

Response: We appreciate the commenters concerns regarding the difficulties that facilities could experience with their EHRs' operability with non-EHR healthcare facilities during an emergency. We acknowledge that EHR technology is in varying stages of development throughout the provider and supplier communities and understand the ramifications of this when patient information and necessary medical documentation needs to be communicated during an emergency.

If a facility using EHRs experiences an emergency where patient information needs to be communicated to a receiving facility that does not support an EHR system, alternate methods such as paper documentation or faxed information can be used. Facilities are encouraged to explore alternate means of communicating this information.

The rule requires a method of sharing patient information and medical documentation to ensure continuity of care as part of their communication plan. Interpretive guidance for this regulation and subsequent surveyor training will be completed after the publication of this rule.

Comment: A few commenters stated that Health Information Exchange (HIE) networks are in varying stages of development and, in some areas, no HIE network is available. Therefore, some of these commenters suggested that CMS work with the Office of the National Coordinator (ONC) to support policies that accelerate the development of a robust infrastructure for HIE networks.

Response: We appreciate this feedback and agree with the commenters. CMS continues to work with the ONC to support and promote the adoption of health information technology and the nationwide development of HIE to improve healthcare. While we are not mandating the use of EHRs through this rule, we encourage facilities to consider the meaningful use of certified EHR technology to improve patient care.

HHS has initiatives designed to encourage HIE among all healthcare providers, including those who are not eligible for the Electronic Health Record (EHR) Incentive Programs, and are designed to improve care delivery and coordination across the entire care continuum. Our revisions to this rule are intended to recognize the advent of electronic health information technology and to accommodate and support adoption of Office of the National Coordinator for Health Information Technology (ONC) certified health IT and interoperable standards. We believe that the use of such technology can effectively and efficiently help facilities and other providers improve internal care delivery practices, support the exchange of important information across care team members (including patients and caregivers) during transitions of care, and enable reporting of electronically specified clinical quality measures (eCQMs). For more information, we direct stakeholders to the ONC guidance for EHR technology developers serving providers ineligible for the Medicare and Medicaid EHR Incentive Programs titled "Certification Guidance for EHR Technology Developers Serving Health Care Providers Ineligible for Medicare and Medicaid EHR Incentive Payments." (*http://www.healthit.gov/sites/default/files/generalcertexchangeguidance_final_9-9-13.pdf*).

In addition, we encourage facilities to engage in healthcare coalitions in their area in effort to identify local best practices and potential examples that may assist them in developing communication plans that include a procedure for sharing information and medical documentation, when necessary, with other healthcare facilities to ensure continuity of care.

Comment: A few commenters discussed the requirements for communication plans as set out in the most recent NFPA® 99–2012 guidelines. Citing the NFPA® 99–2012 requirements for communication plans, the commenters noted that CMS' proposed communication plan requirements are too general by comparison. The commenters stated that this generalization would make it harder to verify that a facility's plan meets the emergency preparedness requirements and would make the verification of adherence to these requirements tedious and subjective. Furthermore, the commenters stated that the proposal mimics the current standard in the NFPA® 99–2012, and may cause misinterpretation and conflict as the regulations change over time.

A commenter stated that some key communication planning items are not included in the proposed rule and are better described in the standard NFPA® 99, "Health Care Facilities Code, 2012 edition."

Response: We appreciate the commenters' feedback about the NFPA® 99–2012 edition. We issued a final rule on May 4, 2016 entitled "Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities" (81 FR 26871), to adopt the 2012 editions of NFPA® 101, "Life Safety Code," and NFPA® 99, "Health Care Facilities Code." We refer readers to that final rule for a discussion of these requirements.

We do not believe that we have been overly prescriptive in our communication plan requirements. Facilities are afforded the flexibility to include more detailed and stringent communication plan policies in their emergency preparedness plan, as long as they meet the minimum requirements described here.

Comment: A commenter recommended that CMS explicitly include social media in the communications plan requirements. The commenter noted that social media has recently proven to be an essential tool for communication during disasters.

Response: We appreciate the commenter's feedback. While we acknowledge the importance of other types of electronic communication and encourage facilities to utilize technology when developing a well-organized communication plan, which may include communication through social media, the regulations list the minimum requirements for a provider's communication plan. We have not prescribed specific communication plans within our regulations and have instead allowed hospitals the flexibility to formulate and maintain their own communication plans. We would expect facilities to choose appropriate ways to communicate with patients or the community as a whole.

Comment: A commenter recommended that CMS encourage the integration of the hospital in the community Joint Information Center, and focus on not only the logistics and infrastructure of communication, but the actual management of messages and act of communicating.

Response: We encourage hospitals to develop an effective communication plan that contains contact information for local emergency preparedness staff and to also have a primary and alternate means for communicating with local emergency management agencies. A hospital's communication plan, for example, may have specific protocols for communicating with a community emergency operations center or joint information center, and if the hospital so chooses, the plan can contain procedures on how to formulate, manage, and deliver messages. As previously stated, the hospital can exceed the minimum standards described here.

Comment: A few commenters requested clarification on the definition of the term "geographic area", as used in the requirement for the backup of electronic information to be stored within and outside of the geographic area where the hospital is located.

Another commenter stated that it is unclear how a facility could demonstrate that any backup system would be sufficiently "geographically remote" from the region and stated that CMS should clearly define the expectations of this section. The commenter also noted that an expectation that facilities establish data farms in extremely remote areas of service was excluded from the ICR burden calculations.

The commenters also expressed concern about the language in the proposed rule which stated that "electronic information would be backed up both within and outside the geographic area where the hospital was located" and questioned what exactly constitutes enough of a geographic separation to meet the intent of the proposed language.

Response: We clarify that we are not requiring facilities to utilize EHRs or electronic systems that would require external backup, off-site storage facilities, or data farms. In meeting the requirement that a hospital have a method for sharing information and medical documentation for patients under the hospital's care, facilities may choose to store or back up electronic information within and outside the geographic area if they determine that this is the best option for their facility to maintain their ability to provide information that can ensure continuity of patient care during a disaster. Facilities may find this strategy useful during an emergency if the facility loses power or needs to be evacuated. However, although we believe that it is a best practice to have an alternate storage location for medical documentation, we are not mandating that facilities store information within and outside the geographic area where the hospital is located. We encourage facilities to consider all options that are available to them to protect their medical documentation to ensure continuity of care should an emergency or disaster occur.

Comment: A commenter recommended that CMS require facilities to address recovery of operations planning in emergency and communications plans.

Response: We agree that it is important for hospitals and other providers and suppliers to consider recovery of operations while planning for an emergency. However, we note that the scope and focus of the emergency preparedness requirements in this regulation are on continuity of operations during and immediately after an emergency. Hospitals and other providers and suppliers may choose, as a best practice, to incorporate recovery of operations in their emergency plans but we note that this is not a requirement that needs to be met in order to be in compliance with these conditions of participation. We refer readers to the resources noted in this final rule on recovery of operations.

Comment: A commenter noted that when large scale events occur, public communication systems are overburdened and ineffective. Furthermore, the commenter noted that although hospitals will have alternate means to communicate through technology such as HAM radio, 800 megahertz (MHz)/ultrahigh frequency (UHF) radio, satellite systems, and Government Emergency Telecommunications Service (GETS), these technologies will not be readily available to the persons that the hospital may be trying to reach. The commenter recommended that CMS focus on the hospital establishing processes to readily communicate with staff, care providers, suppliers, and family.

Response: We understand the commenter's concerns about failures in public communication systems and we agree that hospitals should include processes that would allow for communication with staff, care providers, families, and others who may not have alternative forms of technology such as HAM and satellite systems. However, hospitals should be as well prepared as possible ahead of an emergency or disaster as they attempt to mitigate any potential system failures. We believe that our proposal to require that hospitals develop and maintain a communication plan that includes a means for communicating with hospital staff, and with federal, state, tribal, regional, and local emergency management entities, appropriately helps to prepare hospitals to communicate with the appropriate emergency management officials during an emergency or disaster. We encourage hospitals to consider all types of alternate communication systems and to develop a communication plan that includes procedures on how these alternate communication plans are used, and who uses them. Hospitals may seek information on the National Communication System (NCS), which offers a wide range of National Security and Emergency Preparedness communications services, the Government Emergency Telecommunications Services (GETS), the Telecommunications Service Priority (TSP) Program, Wireless Priority Service (WPS), and Shared Resources (SHARES) High Frequency Radio Program at *http://www.hhs.gov/ocio/ea/National%20Communication%20System/* (click on "services").

Comment: A commenter stated that state, regional and local emergency operations have required the "Chain of Command" process. The commenter notes that facilities should have the flexibility to adhere to the state/regional Chain of Command and that clarification is needed to define the scope of the expectation of the proposed rule.

Response: As previously stated, § 482.15(c) states that hospitals must develop and maintain an emergency preparedness communication plan that complies with both federal and state law. We are not prescribing, nor are we mandating, that hospitals abide by a certain "Chain of Command" process. As long as hospitals are complying with federal and state law, hospitals are given the flexibility in these rules to comply with a "Chain of Command" process that is utilized at their state or local level. We do encourage hospitals to understand National Incident

Management System (NIMS) which provides a common emergency response structure and suggested communications processes that will better support and enable integration with local, tribal, regional, state and federal response operations. We would also expect hospitals that choose to comply with a "Chain of Command" process would include such procedures in their communication plan.

Comment: A commenter recommended that CMS include language in § 482.15(c)(6) requiring the disclosure of patient information to state and local emergency management agencies.

Response: We believe that hospitals should have a means of providing information, as permitted under the HIPAA Privacy Rule, 45 CFR 164.510, in the event of an evacuation and that a hospital should have a means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4). However, we do not believe that it is appropriate to include in these regulations a mandatory requirement that hospitals specifically disclose patient information to state and local health department and emergency management agencies. Hospitals may release patient information during an evacuation or emergency disaster, in compliance with federal and state laws.

Comment: A commenter recommended that CMS include the phrase "and in accordance with state law" in § 482.15(c)(6).

Response: We disagree with the commenter that an additional phrase "and in accordance with state law" should be included in § 482.15(c)(6). We believe that language at § 482.15(c), which states that the hospital must develop and maintain an emergency preparedness communication plan that complies with both federal and state law, sufficiently addresses concerns about hospital compliance with state laws.

Comment: A commenter recommended that CMS consider including non-healthcare facilities in the communication plan, such as child care programs and schools, where children with disabilities and other access and functional needs may be sheltering in place.

Response: We do not believe that it is appropriate to require hospitals to include other providers of services, such as child care programs and schools, in their communication plan in these conditions of participation. However, we have allowed facilities the flexibility and the discretion to include such providers in their communication plans if deemed appropriate for that facility and patient population.

Comment: A commenter stated that communications planning should include equipment interoperability, redundancy, communications, and cyber security provisions. The commenter also stated that the primary and alternate communication systems for hospitals should include interoperability coordination, planning and testing with interdependent healthcare systems, their supporting critical infrastructure systems, and critical supply chains.

Response: We agree with the commenter that hospitals should consider security, equipment interoperability, and redundancy in their emergency preparedness plan. We also agree with the statement that hospitals should plan for and test interoperability of their communication systems during drills and exercises. However, we are allowing facilities flexibility in how they formulate and operationalize the requirements of the communication plan. We have not included specific requirements on cyber security and redundancy. However, we encourage facilities to assess whether their specific facility can benefit from such plans.

Comment: A few commenters requested that CMS provide clarification on which federal laws are referenced in the proposed rule in regards to the proposed communication plan. The commenters wanted to ensure that facilities are aware of, and comply with, all applicable federal regulations. A commenter expressed concern that, without knowing the federal statutes referenced it would be difficult for hospitals to assess whether compliance would be burdensome. A commenter stated that clarifying this statement would assist facilities to determine the real cost of compliance.

Response: As with all CoPs, we expect facilities to adhere to additional federal and state laws that are applicable and necessary to provide quality healthcare. For example, some states might have more stringent requirements for their healthcare facilities and personnel and we would expect the facilities to comply with those requirements. Our CoPs do not preclude facilities from establishing requirements that are more stringent.

We encourage facilities to determine what federal, state, and local laws apply to their specific facility's locations and develop plans that comply with these federal, state, and local emergency preparedness requirements.

Comment: A commenter stated that while most hospitals meet the requirements in the proposed communication plan, the onus should be with the state and not the hospital to determine authorized levels of interoperability with all healthcare partners.

Response: We understand the commenter's concerns about the potential burden on hospitals. However, we believe that hospitals have the ability to maintain an emergency preparedness communication plan while working in conjunction with the federal, state, tribal, regional or local emergency preparedness staff. We expect that hospitals will be able to communicate and coordinate with other healthcare facilities in order to protect patient health and safety during an emergency or disaster event. We continue to support hospitals and other facilities engaging in healthcare coalitions in their area for assistance broadening awareness and collaboration as well as in identifying best practices that can assist them to effectively meet this requirement.

Comment: A commenter stated that annual review requirements are a dated approach to ensuring that policies are kept up-to-date. The commenter recommended that CMS eliminate the annual review requirements and tie the review and revision to the testing process and periodic risk assessment.

Response: We disagree with the commenter's statement that annual review requirements are dated. We believe that hospitals are best prepared to act appropriately and swiftly during an emergency or disaster event with an updated communication plan. Updating the hospital's communication plan, at least annually will account for changes in staff that have occurred during the year at the hospital and at the federal, state, tribal, regional or local level. In addition, hospitals can update their communication plans at any time to incorporate the most recent best practices and lessons learned.

We note that this standard includes the minimum requirements for reviewing and updating a hospital's emergency preparedness communication plan. Hospitals can review and update their communication plan more frequently than annually if they choose to do so. Currently, many hospitals frequently update their contact list to account for staffing changes. Therefore, we continue to believe that hospitals should review and update their communication and emergency preparedness plan at least annually.

Comment: A commenter expressed support for the proposed communication plan for hospitals but stated that an annual update of staff contact information is not frequent enough. The commenter recommended that CMS modify this standard to require that staff information be maintained more often than annually, such as quarterly or semi-annually. The commenter notes that within 1 year, key staff and individual responsibilities that are needed during an emergency can change.

Another commenter recommended that facilities reevaluate and update their emergency and communication plan within 180 days of a specific emergency event.

Response: We thank the commenters for their suggestion. We agree that staff information at hospitals changes frequently and note that, as a best practice, hospitals may choose to consider updating their communication plan more frequently than annually. However, we are requiring that hospitals update their communication plan at least annually, which allows for hospitals to update their emergency contact list quarterly, semi-annually or more frequently if they choose to do so and still maintain compliance with the requirements of this standard. We encourage hospitals to assess whether it is appropriate to update their contact lists annually or more frequently than annually.

In regards to the recommendation that facilities reevaluate and update their emergency and communication plan within 180 days of a specific emergency event, we note that the emergency preparedness CoPs require that hospitals and other providers and suppliers review and update their plans at least annually at a minimum. We are also requiring, at § 482.15(d)(2)(iv), that hospitals analyze the hospital's response to, and maintain documentation of, all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan, as needed. Facilities can choose to review and update their plans more frequently than annually at their own discretion.

After consideration of the public comments we received, we are finalizing our proposal, with the following modifications:

- Revising § 482.15(c) by adding the term "local" to this and parallel provisions throughout the rule to clarify that hospitals must develop and maintain an emergency preparedness communication plan that also complies with local laws.
- Revising § 482.15(c)(4) by replacing the term "ensure" with "maintain."
- Revising § 482.15(c)(5) to clarify that hospitals must develop a means, in the event of an evacuation, to release patient information, as permitted under 45 CFR 164.510(b)(1)(ii).

4. Training and Testing (§ 482.15(d))

We proposed at § 482.15(d) that a hospital develop and maintain an emergency preparedness training and testing program. We proposed to require the hospital to review and update the training and testing program at least annually.

We stated that a well-organized, effective training program must include providing initial training in emergency preparedness policies and procedures. We proposed at § 482.15(d)(1) that hospitals provide such training to all new and existing staff, including any individuals providing services under arrangement and volunteers, consistent with their expected roles, and maintain documentation of such training. In addition, we proposed that hospitals provide training on emergency procedures at least annually and ensure that staff demonstrate competency in these procedures.

Regarding testing, we proposed at § 482.15(d)(2), to require hospitals to conduct drills and exercises to test their emergency plans. We proposed at § 482.15(d)(2)(i) to require hospitals to participate in a community mock disaster drill at least annually. If a community mock disaster drill is not available, we proposed that hospitals should conduct individual, facility-based mock disaster drills at least annually. However, we proposed at § 482.15(d)(2)(ii) that if a hospital experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospital would be exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the actual event.

We proposed at § 482.15(d)(2)(iii) to require hospitals to conduct a paper-based tabletop exercise at least annually. We indicated that the tabletop exercise could be based on the same or a different disaster scenario from the scenario used in the mock disaster drill or the actual emergency. We proposed to define a tabletop exercise as a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

We proposed at § 482.15(d)(2)(iv) that hospitals analyze their response to, and maintain documentation on, all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan as needed.

We received many comments on our proposed changes to require a hospital to develop and maintain an emergency preparedness training and testing program.

Comment: In general, most commenters supported our proposal to require hospitals to develop an emergency preparedness training and testing program. We received a few general comments about the requirement. A commenter stated that training and testing would heighten provider awareness with regard to the facilities' limitations and ultimately ameliorate some of the negative effects of a disaster on continuity of care through quicker decision making. A few commenters expressed concerns about the financial burden that the development of training and testing programs would impose on their facilities. Some agreed that state and local governments may be able to provide training resources for some rural and smaller hospitals and facilities; however, some commenters pointed out that many states and local governments are facing considerable staffing and budget cuts, limiting their resources. In addition, a few commenters provided suggestions for how we could improve the discussion of our proposed requirement within the preamble section of the proposed rule.

Response: We thank the commenters for their support and feedback. We agree that overall emergency preparedness planning will have a positive impact on facilities, suppliers, and the populations that they serve. We recognize the time and financial impact that the development of training and testing programs will impose on facilities, but believe that the benefits of heightened awareness, improved processes, and increased safety and preparedness will ultimately outweigh the burden.

Comment: Many commenters expressed concerns about the varying levels of emergency preparedness experience of hospitals as well as other provider and supplier types. Commenters stated that some providers, hospitals in particular, may have a trained disaster response or planning person on staff. These commenters wanted to know how we will take this into consideration when surveying providers and suppliers on this training and testing requirement.

Response: We believe that this final rule establishes core components of an emergency preparedness program that align to national emergency preparedness standards and can be used not only for hospitals, but across provider and supplier types, while tailoring requirements for individual provider and supplier types to their specific needs and circumstances, as well as the needs of their patients, residents, clients, and participants. We proposed individual requirements for each provider and supplier type that will be surveyed at the individual facility level. As with the standard surveying process, each provider and supplier type will be individually surveyed for their specific training and testing requirements, rather than in comparison to the capabilities of other healthcare settings affected by this regulation. In addition, as discussed earlier, we are finalizing our proposal for an implementation date that is one-year after the effective date of this final rule. This implementation date will allow providers who may not be experienced in emergency preparedness planning, time to access resources and develop plans that best meet their needs. We are not requiring that any facility have a designated staff member responsible for emergency preparedness. However the facility may choose to establish such a position.

Comment: A few commenters recommended that we specifically require that the training and testing program be developed consistent with the principles of the Homeland Security Exercise and Evaluation Program (HSEEP). A commenter believed that our proposed requirement is not specific enough and should lay out exactly what our expectations are for a successful training program and what exactly is required. Another commenter pointed out that, while we referenced the principles of HSEEP in the preamble, we did not require such principles in our regulations. A commenter suggested that we require all healthcare facilities to receive training in an incident command system.

Response: We appreciate the recommendations. The requirements we establish are the minimum health and safety standards that facilities must meet; however, a provider or supplier may choose to set higher standards for its facility. In the proposed rule, we provided facilities with resources and examples to help them begin developing a training and testing program. We do not believe that we should limit the principles/guidelines that a facility may want to utilize when developing its program.

Comment: A commenter supported our proposal for the development of an emergency preparedness training program, but suggested that hospitals and all providers and suppliers include first responders in all aspects of their training program. The commenter stated that the inclusion of first responders would help to ensure consistency, allowing both groups to do their jobs in a more productive and safer manner, ultimately improving communications across the board in the event of an emergency.

Response: We agree that first responders are an essential part of the emergency management community and are relied upon heavily during a man-made or natural disaster. However, we do not have the statutory authority to regulate first responders and emergency management personnel. In an effort to bolster communication and collaboration, we proposed to require that providers and suppliers include in their emergency plan a process for ensuring cooperation and collaboration with local, tribal, regional, state, and federal health department and emergency preparedness officials' efforts. This would include documentation of efforts to contact such officials and, when applicable, their participation in collaborative and cooperative planning efforts. We also encourage providers and suppliers to engage and collaborate with their local healthcare coalition, which commonly includes the health department, emergency management, first responders, and other emergency preparedness professionals.

Comment: A commenter suggested that the requirement for a training and testing program specify that drills and exercises must address varying emergencies supporting the proposed all-hazards approach to planning. The commenter explained that this would include flooding in a portion of a building due to a water line rupture as well as flooding that requires evacuation of patients. Another commenter suggested that the training program should be competency-based. The commenter believed that competencies help connect training and testing, in essence providing a common denominator and language at the facility preparedness level. The commenters also stated that the disaster medicine and public health community has long recognized the importance of competencies, as evidenced by the multiple competency sets developed for disaster health.

Response: While not explicitly stated, we would assume that a hospital's training materials and testing exercises would be reflective of the risk assessment that is required as part of their emergency plan, utilizing an all-hazards approach. In order to accurately assess its plan, a hospital would need to have training and exercises that address realistic threats based on their risk assessment, otherwise the training and testing program would not be effective. The purpose of the training and testing program is to demonstrate the effectiveness of the hospital's emergency plan and to use the results of drills and exercises to improve the hospital's plan. We would also expect that a hospital would want to provide insightful and meaningful training, and would therefore tailor its training materials to the audience receiving the instruction. A hospital may always choose to establish internal facility policies that go beyond the minimum health and safety standards that we are finalizing.

Comment: A few commenters pointed out that many healthcare facilities are actively educating their staff on emergencies specific to their environments and conducting preparedness exercises. Some commenters suggested that annual training would only be appropriate for staff members who may take on positions in an emergency, but would be irrelevant to a large portion of the system's staff.

A few comments stated that our proposal for annual staff training is inappropriate, redundant in many situations, and a waste of scarce healthcare resources. Some commenters recommended that we only require annual training and exercises for those providers that would be instrumental in a disaster and require less frequent training and exercises for those providers that would not be expected to be operational during a disaster.

Response: As evidenced by every new disaster, and by the GAO and OIG reports that we discussed in the proposed rule (See 78 FR 79088), we believe that there is substantial evidence that provider and supplier staff need more training in emergency practices and procedures. Initial and annual staff training promotes consistent staff behavior and increases the knowledge of staff roles and responsibilities during a disaster. To offset some of the financial impact that training may impose on facilities, we have allowed facilities the flexibility to determine the level of training that any staff member may need. A provider could decide to base this determination on the staff member's involvement or expected role during a disaster. In addition, since staff members may be expected to act outside of their usual role during a disaster, providers could also decide to equally train staff on varying functions during a disaster. In this final rule we have revised our proposal to allow for large health systems to develop an integrated emergency preparedness program for all of their facilities, which would include an integrated training program. Therefore, to offset some of the financial burden, facilities that are part of a large health system may opt to participate in their health system's universal training program. However, the training at each separately certified facility must address the individual needs for such facility and maintain individual training records in order to demonstrate compliance.

Comment: A few commenters requested that we clarify what annual training would involve and define the minimum requirements of training needed to meet this annual training requirement.

Response: We are giving facilities the flexibility to determine the focus of their annual training. Because we are requiring that the emergency plan and policies and procedures be updated at least annually, staff would need to be trained on any updates to the emergency plan and policies and procedures. For instance, acceptable annual training could include training staff on new evacuation procedures that were identified in the facility's risk assessment and added to the emergency plan within the last year.

Comment: A commenter did not support our proposed requirement for annual training and stated that a demonstration of skill requires some method of physical validation. The commenter also stated that annual training would be overly burdensome for providers. Another commenter suggested that instead of requiring annual training, we should require annual validation of knowledge through written testing, demonstration, or real-world response based on plans and policies. A commenter expressed support for the intent of the annual training requirement, but encouraged CMS to provide more detail and information related to specific levels of training for individual healthcare workers within a provider or supplier organization. Also, some commenters requested clarification on how staff would demonstrate their knowledge of emergency preparedness.

Response: We thank the commenters for their feedback. We did not specify the content of a facility's annual training. The purpose of the requirement is to ensure that facilities are continually educating their staff on their emergency preparedness procedures and discussing how to implement such procedures during an emergency. We believe that it is up to a provider or supplier to determine what level of training is required of their staff based on their individual emergency plans and policies and procedures. We note that we also proposed to require at § 482.15(d)(1)(iv) that hospitals ensure that staff can demonstrate knowledge of their facility's emergency procedures. We believe that this requirement, in addition to the annual training requirement, requires facilities to ensure that staff is continuously being updated and educated on a facility's emergency procedures and encourages facilities to ensure that the annual trainings are informative and insightful, so that staff can demonstrate knowledge of the procedures. We would also expect that the results of the knowledge check should produce information that can be used to update the emergency plan and any future training.

Comment: Several commenters agreed that training of staff and volunteers is a significant aspect of emergency planning and pointed out that, in a disaster, many members of the hospital staff will continue to perform the same job they do every day. Commenters pointed out that most hospitals already provide basic awareness level training to staff as well as more comprehensive training for employees who are assigned a leadership or management role in the hospital's incident command system during an emergency.

Several commenters requested that we clarify who exactly we are referring to in paragraph § 482.15(d)(1)(i), which states that individuals providing services under arrangement must receive initial training in emergency preparedness policies and procedures. Several commenters requested that we provide examples to eliminate any confusion about the use of the phrase. Other commenters stated that they believed that CMS was referring to groups of physicians, other clinicians, and others who provide services essential for adequate care of patients and maintenance of operation of the facilities, but whose relationship with the hospital is by contract rather than through employment or voluntary status. The commenters pointed out that there may be others with whom a hospital would have an arrangement for the provision of services, but these may be services that would not be essential during the course of a disaster. For example, the commenters explained that hospitals often have arrangements for servicing of office equipment, provision of staff training and education, grounds keeping, and so forth. The commenters stated that they do not believe it was our intent for all personnel covered by these arrangements to be trained for emergency preparedness, but would appreciate some clarification.

Several commenters recommended that we allow hospitals the flexibility to identify outsourced services that would be essential during a disaster and allow the hospital to identify which of these contracted individuals should receive training. Furthermore, a commenter posed a set of specific scenarios for us to consider, including whether the employees of a contracted food service, or a contracted plumber or electrician would need to have emergency preparedness training before they are able to work in the hospital. Similarly, this commenter believed that the language, as proposed, needed to be clarified.

In addition, a commenter requested that we further define what we mean by "volunteers" who would need to be trained. The commenter stated that the term was vague and questioned whether every volunteer would need training, and if so, what level of training. The commenter also inquired about a requested time frame for volunteers to complete training and how often volunteers would be required to be retrained. The commenter pointed out that volunteers are under no obligation to report for duty and cannot be relied upon to perform specified responsibilities during a disaster.

Finally, a commenter requested that we include a definition of "staff" in our proposal to require staff training, since many inpatient hospital-based specialists, such as hospitalists or neonatologists, now provide much of the inpatient medical care. The commenter also suggested that we require hospitals to identify individuals on staff and under contract that would need basic training, as well as staff that would likely manage an emergency event. The commenter suggested that we require hospitals to have a documented training plan for individuals with key responsibilities. The commenter also stated that hospitals should not be required to train all staff, contractors, and volunteers given that the costs associated with such training would far exceed the benefit in times of scarce resources.

Response: We appreciate all of the detailed feedback that we received from commenters on this requirement. The term "staff" refers to all individuals that are employed directly by a facility. The phrase "individuals providing services under arrangement" means services furnished under arrangement that are subject to a written contract conforming with the requirements specified in section 1861(w) of the Act. According to our regulations, governing boards, or a legally responsible individual, ensures that a facility's policies and procedures are carried out in such a manner as to comply with applicable federal, state and local laws. We believe that anyone, including volunteers, providing services in a facility should be at least annually trained on the facility's emergency preparedness procedures. As past disasters have shown, emergency situations or disasters can be either expected or unexpected. Therefore, training should be made available to everyone associated with the facility, and it is up to the facility to determine the level to which any specific individual should be trained. One way this could be determined is by that individual's involvement or expected role during an emergency. We stated at § 482.15(d)(1)(i) that training should be provided consistent with facility staff's expected roles. To mitigate costs it may be beneficial for facilities to take this approach when establishing their training programs. In addition, as we state elsewhere in this preamble, we encourage facilities to participate in healthcare coalitions in their area. Depending on their duties during an emergency, a facility may determine that documented external training is sufficient to meet the facility's requirements.

Comment: Many commenters supported the requirement for participation in a community drill/exercise and stated that it would better prepare both facility staff and patients regarding procedures in an actual emergency. However, a few commenters requested clarification of the requirement. Specifically, some commenters requested that we clarify what we meant by "community," while another commenter encouraged CMS to allow organizations to define their community as they saw fit rather than based on geographical locations. A commenter questioned if standard state-required emergency drills would meet the requirement of a community disaster drill. The commenter noted that in their state, all facilities are required to participate in a statewide tornado drill that evaluates the facility and staff on their ability to recognize the threat alert and respond to the alert in accordance with their emergency plan. Another commenter requested that we specify how intensive an exercise would need to be in order to meet the new requirements.

Response: We understand that many disasters, such as floods, can involve a wide geographic area. In addition, we also recognize that many hospitals and various providers operate as part of a large health system. However, we would still expect a hospital or other healthcare facility to consider its physical location and the individuals who reside in their area when conducting their community involved testing exercises. We did not define "community", to afford providers the flexibility to develop disaster drills and exercises that are realistic and reflect their risk assessments. However, the term could mean entities within a state or multi-state region. The goal of the provision is to ensure that healthcare providers collaborate with other entities within a given community to promote an integrated response. In the proposed rule, we indicated that we expected hospitals and other providers to participate in healthcare coalitions in their area for additional assistance in effectively meeting this requirement. Conducting exercises at the healthcare coalition level could help to reduce the administrative burden on individual healthcare facilities and demonstrate the value of connecting into the broader medical response community, as well as the local health and emergency management agencies, during emergency preparedness planning and response activities. Conducting integrated planning with state and local entities could identify potential gaps in state and local capabilities that can then be addressed in advance of an emergency. Regional planning coalitions (multi-state coalitions) meet and carry out exercises on a regular basis to test protocols for state-to-state mutual aid. The members of the coalitions are often able to test incident command and control procedures and processes for sharing of assets that promote medical surge capacity.

Comment: Several commenters indicated that the term "mock" disaster drill is not a common term in emergency exercise vocabulary. Some recommended that we use the Homeland Security Exercise and Evaluation Program vocabulary, "disaster drill exercise." Another commenter suggested that we use the preferred term of "functional" or "full-scale exercise." Commenters believed that these terms are clearer in regard to the expectations for hospitals and other providers.

Response: We appreciate the suggestions and agree that the term could be revised to more appropriately reflect the intention of the requirement. In contrast to an instructor led tabletop exercise utilizing discussion, the requirement for participation in a community disaster drill exercise is meant to require facilities to simulate an anticipated response to an emergency involving their actual operations and the community. We are aware that there are several current terms used to describe types of exercises and understand how the use of the term "mock disaster drill" may leave room for confusion. However, we note that industry terms evolve and change, so there is a need to ensure that the terms in our regulations are broad and inclusive, with a "plain language" meaning to the extent possible. In this final rule, we are revising our proposal by replacing the term "community mock disaster drill" with "full-scale exercise." We believe that this term is broad enough to encompass the suggested terms from commenters, as well as an accurate description of the intent behind the provision.

Comment: A few commenters requested further clarification as to when a facility-based disaster drill could replace a community disaster drill. Most of the commenters pointed out that smaller hospitals and those providers outside of the hospital may not have close ties to emergency responders or community agencies that organize drills. Another commenter wanted to know what requirements would be placed on state and local governments to include all provider types in their disaster drill planning.

Response: We would expect that a facility-based disaster drill would meet the requirement for a community disaster drill if a community disaster drill were not readily accessible. For example, a rural provider located in a remote location might have limited ability to participate in a community disaster drill and would conduct a facility-based drill in order to comply with this requirement. The intention of this requirement is to not only assess the feasibility of a provider's emergency plan through testing, but also to encourage providers to become engaged in their community and promote a more coordinated response. Therefore, smaller facilities without close ties to emergency responders and community agencies are encouraged to reach out and gain awareness of the emergency resources within their community. We note that CMS does not regulate state and local governments' disaster planning activities.

Comment: Most commenters supported our proposal to exempt providers from the community mock drill requirement if the facility had experienced a disaster in the past year. A few commenters requested clarification on what would be considered activation of a facility's plan. The commenter wondered if there would have to be involvement of local emergency management or whether the activation could be made by the facility itself.

Response: In the proposed rule we stated that for the purpose of the proposed regulation, "emergency" or "disaster" can be defined as an event affecting the overall target population or the community at large that precipitates the declaration of a state of emergency at a local, state, regional, or national level by an authorized public official such as a governor, the Secretary of HHS, or the President of the United States (see 78 FR 79084). In addition, as noted earlier in the general comments section of this final rule, an emergency event could also be an event that affects the facility internally as well as the overall target population or the community at large. While allowing for the exemption of the community disaster drill requirement when an actual emergency event is experienced, we also proposed to require that facilities maintain documentation of all exercises and emergency events. To that extent, upon survey, a facility would need to show that an emergency event had occurred and be able to demonstrate how its emergency plan was put into action as a result of the emergency event.

Comment: Many commenters requested clarification of our proposal to require one tabletop exercise annually. Commenters stated that we did not provide a clear expectation of what tabletop exercise would meet our requirements. Commenters also recommended that we note that tabletop exercises could be computer-simulated and that we should not limit the requirement to paper-based tabletop exercises. A commenter noted that we were silent regarding who could serve as a facilitator for the tabletop exercise and questioned if a facilitator could be a staff member.

Response: In the proposed rule, we indicated that we would define a tabletop exercise as a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. We believe that this would also include the use of computer-simulated exercises. We also suggested that providers and suppliers consider using, among other resources, the tabletop exercise toolkit developed by the New York City Department of Health and Mental Hygiene's Bureau of Communicable Diseases (September 2005, found at: *http://www.nyc.gov/html/doh/downloads/pdf/bhpp/bhpp-train-hospital-toolkit-01.pdf* or the RAND Corporation's 2006 tabletop exercise technical report (*http://www.rand.org/pubs/technical_reports/2006/RAND_TR319.pdf*) to help them comply with this requirement. We were purposely silent on who could facilitate a tabletop exercise and believe that decision should be left to the discretion of the facility.

Comment: A commenter suggested that we require the tabletop exercises to focus on decompression of existing staffed beds (that is, how to move less critically ill patients out of the facility), identification of alternate space within a facility or adjacent campus buildings, and sheltering in place. The commenter also pointed out that many accrediting organizations require medical surge exercises, which could be combined in a decompression/surge scenario to incorporate issues that could occur in a real life event and might be a better focus for facility exercises.

Response: We appreciate the commenter's suggestion. We understand that depending on varying factors, such as provider type, size of facility, complexity of offered services, and location, facilities will have differing risks and needs. Therefore, we believe that facilities should have the flexibility to determine the focus of their exercises based upon their individual risk assessment, emergency plan, and policies and procedures. We note that, without more information about the specific medical surge exercise, in order to assess compliance, facilities would need to be able to demonstrate to surveyors how the medical surge exercise appropriately tests the facility's emergency preparedness plan.

Comment: Multiple commenters expressed their concern regarding our intent to require both a community mock disaster drill and a tabletop exercise every year and questioned the need for both. We received conflicting comments about the accessibility and burden of participating in a community mock disaster drill. While a few commenters stated that a community mock drill would be burdensome and require significant planning and time, other commenters stated that most organizations have several opportunities to participate in some type of integrated preparedness training exercise within their community every year. We also received conflicting comments about the effectiveness of tabletop exercises. A few commenters stated that tabletop exercises do not adequately determine the functionality of an emergency plan and can reduce a facility's level of preparedness. Another commenter stated that tabletop exercises are an efficient way to test policies that are currently in the plan and ensure that staff is knowledgeable about current operating procedures. Another commenter stated that tabletop exercises add value, but that a full-scale disaster drill is considered a best practice. A commenter stated that the requirement for a tabletop exercise is impractical for smaller providers and suggested that we base the necessity of the requirement on facility size.

Many commenters stated that most accrediting organizations and emergency response organizations require that providers test their emergency plans at least twice annually through fully operational exercises; these organizations do not accept a tabletop exercise to satisfy this requirement. These commenters recommended that we require two disaster drills annually and eliminate the requirement for a tabletop exercise. Furthermore, the commenters recommended that one of the drills be a community drill. Commenters also suggested that we exempt those facilities that participate in two annual disaster drills from the tabletop exercise requirement. A commenter suggested that we require a community mock disaster drill 1 year and a tabletop exercise the next year, rather than both in the same year. A commenter stated that conducting a disaster drill would require a good amount of planning and interruption of clinical services, therefore reducing this requirement to every other year would reduce the burden on the facility. Another commenter requested that we allow providers the flexibility to determine the type of drill or exercise needed to test their plan in accordance with their internal policies and procedures.

Response: We continue to believe that both a disaster drill and a tabletop exercise are effective in emergency preparedness planning. We understand that while beneficial, drills and exercises have financial implications that can be burdensome for some provider and supplier types. Many commenters observed that most hospitals are currently conducting drills and exercises, so any additional financial impact would be minimal. Therefore, in this final rule we are revising our proposed provision at § 482.15(d)(2) to require facilities to conduct one full-scale exercise and an additional exercise of their choice, which could be a second full-scale exercise or a tabletop exercise. We note that the full-scale exercise must be community-based unless a community exercise is not available. Facilities may opt to conduct more exercises, as needed, to improve their emergency plans and prepare their staff and patients and are encouraged to include community-based partners in all of their additional exercises where appropriate. We believe that this revision will give facilities the ability to determine which exercise is most beneficial to them as they consider their specific needs.

Comment: A commenter suggested that CMS require providers of all types to participate at least once annually in instructional programs, presentations, or discussion forums delivered by state health departments.

Response: We do not believe that it is appropriate to compel providers to attend instructional programs, presentations, or discussion forums delivered by state health agencies. However, as noted in § 482.15, hospitals must comply with all applicable federal and state emergency preparedness requirements. Therefore, if a hospital is located in a state that mandates that hospitals participate in emergency preparedness instructional programs, the hospital must comply with that state's laws. In addition, if hospitals' management determines such programs to be beneficial to such hospitals in development or maintenance of their emergency preparedness plans, such hospitals have the discretion, under these requirements, to attend such programs as they see fit, or they can incorporate such requirements into their training programs. It is not a requirement of these CoPs that hospitals attend programs overseen by state health departments.

Comment: A commenter suggested that we require completion of after-action reports (AARs) and Improvement Plans (IP) following the completion of drills, exercises, and real events. The commenter also suggested that these documents be made available for surveyors. In addition, the commenter indicated that subsequent exercises and retesting should also be required to demonstrate that improvements were successfully made.

Response: We proposed to require at § 482.15(d)(2)(iv) that hospitals analyze their response to, and maintain documentation of, all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan, as needed. Demonstrating the thorough completion of an AAR or IP would meet this requirement; however, we are not requiring completion of specific reports, in order to give facilities some flexibility in this area. In addition, as an example, we provided a link to the CMS developed Health Care Provider AAR/IP template in the proposed rule, which is a voluntary and user-friendly tool for healthcare providers to use to document their performance during emergency planning exercises and real emergency events, to inform recommendations for improvements for future performance. We indicated that, while we do not mandate the use of this template, thorough completion of the template would comply with our requirements for provider exercise documentation. Lastly, we believe our proposed requirement at § 482.15(d)(2)(i) and (iii) that a disaster drill and a tabletop exercise be conducted annually addresses the commenter's concern about subsequent exercises and retesting since a facility can test any problems it identifies in an upcoming testing exercise.

Comment: We received a few comments on our proposed requirement for hospitals to analyze the hospital's response to, and maintain documentation for, all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan, as needed. A commenter questioned how long after a training the documentation of such training would need to be retained. Another commenter recommended that, if a hospital were to experience two or more actual emergencies and performs an after-action review of its emergency plan, it should be exempt from this requirement.

Response: We believe that this requirement is necessary to ensure that hospitals are benefiting from the lessons learned through testing their plans and revising them as necessary, based on these lessons. We believe that, if a hospital experiences an actual emergency and develops an after-action review, it would be practical for the hospital to use this as an opportunity to revise and update their plan accordingly. In addition, we would expect a facility to maintain training documentation to demonstrate that it has met the training requirements. We note that hospitals are required at § 482.15(d) to update and review their training and testing program at least annually.

In summary, after consideration of the public comments, we are finalizing our proposal for hospitals to develop and maintain an emergency preparedness training and testing program as proposed, with the following exceptions:

- Revising § 482.15(d) by adding that each hospital's training and testing program must be based on the hospital's emergency plan, risk assessment, policies and procedures, and communication plan.
- Revising § 482.15(d)(1)(iv) by replacing the phrase "Ensure that staff can demonstrate" with the phrase "Demonstrate staff knowledge."
- Revising § 482.15(d)(2) by replacing the term "community mock disaster drill" with "full-scale exercise."
- Revising § 482.15(d)(2) to allow a hospital to choose the type of exercise it will conduct to meet the second annual testing requirement.

5. Emergency Fuel and Generator Testing (§ 482.15(e))

We proposed at § 482.15(e)(1)(i) that hospitals store emergency fuel and associated equipment and systems as required by the 2000 edition of the Life Safety Code (LSC) (NFPA®101) of the NFPA®. We note that CMS recently issued a final rule on May 4, 2016 entitled "Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities" (81 FR 26872), to adopt the NFPA® 2012 edition of the LSC and the "Health Care Facilities Code." The current LSC states that a hospital's alternate source of power (for example, a generator), and all connected distribution systems and ancillary equipment, must be designed to ensure continuity of electrical power to designated areas and functions of a healthcare facility. Also, the LSC states that the rooms, shelters, or separate buildings housing the emergency power supply must be located to minimize the possible damage resulting from disasters such as storms, floods, earthquakes, tornadoes, hurricanes, vandalism, sabotage and other material and equipment failures.

In addition to the emergency power system inspection and testing requirements found in NFPA® 99, "Health Care Facilities Code," NFPA® 101,"Life Safety Code," and NFPA® 110, "Standard for Emergency and Standby Power Systems," we proposed that hospitals test their emergency and stand-by-power systems for a minimum of 4 continuous hours every 12 months at 100 percent of the power load the hospital anticipates it will require during an emergency.

We also proposed emergency and standby power requirements for CAHs and LTC facilities. As such, we requested information on this proposal, in particular on how we might better estimate costs in light of the existing LSC requirements, as well as other state and federal requirements.

Comment: We received a large number of comments from individual hospitals as well as national and state organizations that expressed concern with the proposed requirement for hospitals, CAHs and LTC facilities to test their generators. The commenters recommended that we continue to refer to the current NFPA® standards for generator testing, along with manufacturers' recommendations. Many commenters stated that there was not enough empirical data to support the proposed additional testing requirements. They further stated that there is no evidence that additional annual testing would result in more reliable generators. A commenter stated that a survey of hospitals affected by Hurricane Sandy did not indicate that increased testing would prevent generator failure during an actual disaster (Flannery, Johnathan, ASHE Advocacy Report 2013, pages 34–37) (“ASHE Report”). Other commenters stated that hospitals already test generators monthly as well as a 4 hour test every 3 years and, in their opinion, this testing schedule is sufficient. Some commenters stated that mandating additional testing would further burden already strained budgets because many healthcare facilities have more than one generator. They stated that the additional testing would cause unnecessary wear and tear on the equipment. Also, complying with the requirement for additional testing in certain geographical locations, such as California, could increase air pollution and the potential for some facilities to be fined by the EPA for emitting additional carcinogens in the air. Another commenter raised concerns that this increase in operational time may require additional guidance or permit validation from the Environmental Protection Agency (EPA) due to the increase in emissions.

Response: We appreciate the commenters concerns on this issue. As we discussed in the proposed rule, the purpose of the proposed change in the testing requirement was to minimize the issue of inoperative equipment in the event of a major disaster, as occurred with Hurricane Sandy. The September 2014 report of the Office of Inspector General (OIG) entitled, “Hospital Emergency Preparedness and Response During Hurricane Sandy” (OIG, OEI–06–13–00260, September 2014) stated that 89 percent of hospitals reported experiencing critical challenges during Sandy, “such as electrical and communication failures, to community collaboration issues over resources, such as fuel, transportation, hospital beds, and public shelters.” According to a survey conducted by The American Society for Healthcare Engineering (ASHE) of its member facilities affected by Hurricane Sandy (ASHE Report pages 34–37), 35 percent of the survey respondents reported that they were without power for a period of time that ranged from 30 minutes to over 150 hours. However, ASHE’s survey concluded that there is no indication that equipment failure could have been anticipated by increasing the frequency of generator testing.

We also appreciate the commenters that pointed out the logistical and budgetary challenges for the healthcare facilities that would be affected by this rule. After carefully considering all of the comments we received and reviewing reports on Hurricane Sandy and Hurricane Katrina (Live Science, “Why power is So Tricky for Hospital During Hurricanes”, Rachael Rettner, November 1, 2012 see *http://www.livescience.com/24489-hospital-power-outages-hurricane-sandy.html*), we believe that there are not sufficient data to assume that additional testing would ensure that generators would withstand all disasters, regardless of the amount of testing conducted prior to an actual disaster. Therefore, we have decided against finalizing the proposed requirement for additional generator testing at this time. We would expect facilities that have generators to continue to test their equipment based on NFPA® codes in current general use (2012 NFPA® 99, 2010 NFPA® 110 and 2012 NFPA® 101) and manufacturer requirements. Accordingly, we have revised § 482.15(e)(1) and (2) by removing the additional testing requirements and adding a new paragraph (h) which incorporates by reference the 2012 version the NFPA® 99, 2010 NFPA® 110 and 2012 NFPA® 101. As discussed in this final rule, we are also removing the additional generator testing requirements for CAHs and LTC facilities.

Comment: Several commenters stated that CMS standards regarding the location and maintenance of generators should be aligned as much as possible with existing standards, laws and regulations, to avoid conflict and confusion; and that the standards should be evaluated and updated periodically to reflect new knowledge and advances in technology. Many commenters agree with the proposed rule that would require a hospital’s generator to be located in accordance with the requirements found in NFPA® 99, NFPA® 101, and NFPA® 110. Furthermore, they commented that CMS should be aligned with NFPA® in how it implements these standards. They stated that requirements already exist through NFPA® and local building codes, and that facilities currently comply with all applicable requirements. They also stated that the requirement for all emergency generators to be located in an area that is free from possible flooding should only apply to new installations, construction or renovation of existing structures. While no empirical data were provided, commenters claimed that relocation of existing equipment and systems would be cost-prohibitive.

Response: We appreciate the support of the commenters that agreed with the proposed requirement that generators be located in accordance with the requirements found in NFPA® 99, NFPA® 101, and NFPA® 110. These codes require hospitals that build new structures, renovate existing structures, or install new generators to place backup generators in a location that would be free from possible flooding and destruction. As such, the CMS requirements are aligned with the Life Safety Code (NFPA® 101), (which has been generally incorporated into CMS regulations) which cross-references 2012 NFPA® 99 and NFPA® 110, at § 482.15.

Comment: A few commenters recommended that CMS consider bringing any additional generator requirement to the NFPA® Technical Committees that maintain standards for emergency and stand-by power.

Response: The NFPA® is a private, nonprofit organization dedicated to reducing loss of life due to fire and other disasters. We have incorporated some of NFPA’s codes, by reference, in our regulations. The statutory basis for incorporating NFPA’s Codes for our providers and suppliers is the Secretary’s general authority to stipulate such additional regulations for each type of Medicare and Medicaid participating facility as may be necessary to protect the health and safety of patients. In addition, CMS has discretionary authority to develop and set forth health and safety regulations that govern providers and suppliers that participate in the Medicare and Medicaid programs.

Comment: A few commenters stated that facilities should be required to have a backup plan that addresses the loss of power in a way that would allow them to continue operations without outside electricity. The commenter stated that this could be addressed a number of ways, including by diverting patients to a nearby facility within a reasonable commuting distance that has sufficient power for the facility to treat patients.

Response: We agree with the commenters. We would encourage facilities to develop an emergency plan that explores the best case scenarios to ensure optimum protection for patients and residents during an emergency. There are times when we would expect a facility to shelter in place and other times when it might be more feasible to evacuate. However, a hospital, or other inpatient provider, is likely to have inpatients at the beginning of a disaster, even when evacuation is planned. Therefore, the facility must be able to provide continued operations until all its patients have been evacuated and its operations cease.

Comment: A few commenters stated that alternate sources of energy to meet all regulatory requirements are currently available through emergency generators. They stated that it is neither practical nor prudent to require an emergency generator at all healthcare facilities, some of which simply close or relocate during a power loss.

Response: We proposed that the requirements for an emergency generator and onsite fuel source to power the emergency generator would apply only to hospitals, CAHs and LTC facilities. We did not include other providers/suppliers discussed in the proposed rule.

Comment: Several commenters opposed requiring facilities that maintain an onsite fuel supply to maintain a quantity of fuel capable of sustaining emergency power for the duration of the emergency or until likely resupply. The commenter pointed out that this approach does not consider the situation in which a hospital or LTC facility would evacuate or close during a prolonged emergency. A few commenters questioned how long a hospital should provide or maintain alternate sources of energy. Another commenter stated that what a facility anticipates it will need during "an emergency" does not necessarily match its in-house generator's capacity. A facility gap analysis would define anticipated need per planned for emergency, and a facility's in-house unit may be ample for some scenarios and not for others. A gap analysis may identify times when evacuation is recommended versus other scenarios when in-house capacity is ample to sustain operations.

Response: We appreciate all of the comments on this proposal. We realize that it would be difficult, if not impractical in certain circumstances, for a facility to have a fuel supply that would be sufficient for the duration of all disasters because the magnitude of the disaster might require facilities to evacuate patients/residents. After a careful evaluation of the comments, we have changed the final rule to require a hospital, CAH, or LTC facility to have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- Revising § 482.15(e)(2)(i) by removing the requirement for an additional 4 hours of generator testing and clarifying that facilities must meet the requirements of NFPA® 99 2012 edition, NFPA® 101 2012 edition, and NFPA® 110 2010 edition.
- Revising § 482.15(e)(3) by removing the requirement that hospitals maintain fuel onsite and clarifying that hospitals must have a plan to maintain operations unless the hospital evacuates.
- Adding a new § 482.15(h) to incorporate by reference the requirements of NFPA® 99, NFPA® 101, and NFPA® 110.

D. Emergency Preparedness Regulations for Religious Nonmedical Health Care Institutions (RNHCIs) (§ 403.748)

Section 1861(ss)(1) of the Act defines the term "Religious Nonmedical Health Care Institution" (RNHCI) and lists the requirements that a RNHCI must meet to be eligible for Medicare participation. We have implemented these provisions in 42 CFR part 403, subpart G, "Religious Nonmedical Health Care Institutions Benefits, Conditions of Participation, and Payment." As of June 2016, there were 18 Medicare-certified RNHCIs that were subject to the RNHCI regulations.

A RNHCI is a facility that is operated under all applicable federal, state, and local laws and regulations, which provides only non-medical items and services on a 24-hour basis to beneficiaries who choose to rely solely upon a religious method of healing and for whom the acceptance of medical services would be inconsistent with their religious beliefs. The religious non-medical care or religious method of healing means care provided under established religious tenets that prohibit conventional or unconventional medical care for the treatment of the patient and exclusive reliance on religious activity to fulfill a patient's total healthcare needs.

The RNHCI does not furnish medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs or biologicals) to its patients. RNHCIs must not be owned by, or under common ownership or affiliated with, a provider of medical treatment or services.

We proposed to expand the current emergency preparedness requirements for RNHCIs, which are located within § 403.742, Condition of participation: Physical Environment, by requiring RNHCIs to meet the same proposed emergency preparedness requirements as we proposed for hospitals, subject to several exceptions.

The existing "Physical environment" CoP at § 403.742(a)(1) currently requires that the RNHCI provide emergency power for emergency lights, for fire detection and alarm systems, and for fire extinguishing systems. Existing § 403.742(a)(4) requires that the RNHCI have a written disaster plan that addresses loss of water, sewage, power and other emergencies. Existing § 403.742(a)(5) requires that a RNHCI have facilities for emergency gas and water supply. We proposed relocating the pertinent portions of the existing requirements at § 403.742(a)(1), (4), and (5) at proposed § 403.748(a) and (b)(1).

Proposed § 403.748(a)(1) would require RNHCIs to consider loss of power, water, sewage and waste disposal in their risk analysis. The proposed policies and procedures at § 403.748(b)(1) would require that RNHCIs provide for subsistence needs of staff and patients, whether they evacuate or shelter in place, including, but not limited to, food, water, sewage and waste disposal, non-medical supplies, alternate sources of energy for the provision of electrical power, the maintenance of temperatures to protect patient health and safety and for the safe and sanitary storage of such provisions, gas, emergency lights, and fire detection, extinguishing, and alarm systems.

The proposed hospital requirement at § 482.15(a)(1) would be modified for RNHCIs. We proposed at § 403.748(a)(1) to require RNHCIs to consider loss of power, water, sewage and waste disposal in their risk analysis. At § 403.748(b)(1)(i) for RNHCIs, we proposed to remove the terms "medical and nonmedical" to reflect typical RNHCI practice, since RNHCIs do not provide most medical supplies. At § 482.15(b)(3), we proposed that hospitals have policies and procedures for the safe evacuation from the hospital, which would include consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance. At § 403.748(b)(3), we proposed to incorporate this hospital requirement for RNHCIs but to remove the words "and treatment" to more accurately reflect that medical care is not provided in a RNHCI.

We proposed at § 403.748(b)(5) to remove the term "health" from the proposed hospital requirement for "health care documentation" to reflect the non-medical care provided by RNHCIs.

The proposed hospital requirements at § 482.15(b)(6) would require hospitals to have policies and procedures to address the use of volunteers in an emergency or other staffing strategies, including the process and role for integration of state or federally designated healthcare professionals to address surge needs during an emergency. For RNHCIs, we proposed at § 403.748(b)(6) to use the hospital provision, but remove the language, "including the process and role for integration of state or federally designated healthcare professionals" since it is not within the religious framework of RNHCIs to integrate care issues for their patients with healthcare professionals outside of the RNHCI industry.

The proposed hospital requirements at § 482.15(b)(7) would require that hospitals develop arrangements with other hospitals and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to hospital patients. For RNHCIs, at § 403.748(b)(7), we added the term "non-medical" to accommodate the uniqueness of the RNHCI non-medical care.

The proposed hospital requirement at § 482.15(c)(1) would require hospitals to include in their communication plan: Names and contact information for staff, entities providing services under agreement, patients' physicians, other hospitals, and volunteers. For RNHCIs, we proposed substituting "next of kin, guardian or custodian" for "patients' physicians" because RNHCI patients do not have physicians.

Finally, unlike the proposed regulations for hospitals at § 482.15(c)(4), we proposed at § 403.748(c)(4), we propose to require RNHCIs to have a method for sharing information and care documentation for patients under the RNHCIs' care, as necessary, with healthcare providers to ensure continuity of care, based on the written election statement made by the patient or his or her legal representative. Also, at proposed § 403.748(c)(4), we removed the term "other" and "health" from the requirement for sharing information with "other health care providers" to more accurately reflect the care provided by RNHCIs.

At § 482.15(d)(2), "Testing," we proposed that hospitals would be required to conduct drills and exercises to test their emergency plan. Because RNHCIs have such a narrow role and provide such a unique service in the community, we believe RNHCIs would not participate in performing such drills. We proposed that RNHCIs be required only to conduct a tabletop exercise annually. Likewise, unlike our proposal for hospitals at § 482.15(d)(2)(i), we did not propose that the RNHCI conduct a community mock disaster drill at least annually or conduct an individual, facility-based mock disaster drill. Although we proposed for hospitals at § 482.15(d)(2)(ii) that, if the hospital experiences an actual natural or man-made emergency, the hospital would be exempt from engaging in a community or individual, facility-based mock disaster drill for 1 year following the onset of the actual event, we did not propose this for RNHCIs.

At § 482.15(d)(2)(iv), we proposed to require hospitals to maintain documentation of all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan, as needed. Again, at § 403.748(d)(2)(ii), for RNHCIs, we proposed to remove reference to drills.

Currently, at § 403.724(a), we require that an election be made by the Medicare beneficiary or his or her legal representative and that the election be documented in a written statement that the beneficiary: (1) Is conscientiously opposed to accepting non-excepted medical treatment; (2) believes that non-excepted medical treatment is inconsistent with his or her sincere religious beliefs; (3) understands that acceptance of non-excepted medical treatment constitutes revocation of the election and possible limitation of receipt of further services in a RNHCI; (4) knows that he or she may revoke the election by submitting a written statement to CMS, and (5) knows that the election will not prevent or delay access to medical services available under Medicare Part A in facilities other than RNHCIs. Thus, at § 403.748(c)(4), we proposed that such election documentation be shared with other care providers to preserve continuity of care during a disaster or emergency.

We did not receive any comments that specifically addressed the proposed rule as it related to RNHCIs. However, after consideration of the general comments we received on the proposed rule, as discussed in the hospital section (section II.C. of this final rule), we are finalizing the proposed emergency preparedness requirements for RNHCIs with the following modifications in response to general comments made with respect to all facilities:

- Revising the introductory text of § 403.748 by adding the term "local" to clarify that RNHCIs must also comply with local emergency preparedness requirements.
- Revising § 403.748(a)(4) by deleting the term "ensuring" and replacing the term "ensure" with "maintain."
- Revising § 403.748(b)(2) to remove the requirement for RNHCIs to track staff and patients after an emergency and clarifying that in the event that staff and patients are relocated during an emergency, the RNHCI must document the specific name and location of the receiving facility or other location for sheltered patients and on-duty staff who leave the facility during an emergency.
- Revising § 403.748(b)(5)(iii) and (b)(7) to remove the term "ensure."
- Revising § 403.748(c) by adding the term "local" to clarify that the RNHCI must develop and maintain an emergency preparedness communication plan that also complies with local laws.
- Revising § 403.748(c)(5) to clarify that RNHCIs must develop a means, in the event of an evacuation, to release patient information, as permitted under 45 CFR 164.510(b)(1)(ii).
- Revising § 403.748(d) by adding that each RNHCI's training and testing program must be based on the RNHCI's emergency plan, risk assessment, policies and procedures, and communication plan.
- Revising § 403.748(d)(1)(iv) by replacing the phrase "ensure that staff can demonstrate" with the phrase "demonstrate staff."

E. Emergency Preparedness Regulations for Ambulatory Surgical Centers (ASCs) (§ 416.54)

Section 1833(i)(1)(A) of the Act authorizes the Secretary to specify those surgical procedures that can be performed safely in an ASC. The surgical services performed in ASCs are scheduled, elective, procedures for non-life-threatening conditions that can be safely performed in a Medicare-certified ASC setting.

Section 416.2 defines an ambulatory surgical center (ASC) as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, and in which the expected duration of services would not exceed 24 hours following an admission.

As of June 2016 there were 5,485 Medicare certified ASCs in the U.S. The ASC Conditions for Coverage (CfCs) at 42 CFR part 416, subpart C, are the health and safety standards a facility must meet to obtain Medicare certification. Existing § 416.41(c) requires ASCs to have a disaster preparedness plan. This existing requirement states the ASC must: (1) Have a written disaster plan that provides for the emergency care of its patients, staff and others in the facility; (2) coordinate the plan with state and local authorities; and (3) conduct drills at least annually, complete a written evaluation of each drill, and promptly implement any correction to the plan. Since the proposed requirements are similar to and would be redundant with existing rules, we proposed to remove existing § 416.41(c). Existing § 416.41(c)(1) would be incorporated into proposed § 416.54(a), (a)(1), (2), and (4). Existing § 416.41(c)(2) would be incorporated into proposed § 416.54(a)(4) and (c)(2). Existing § 416.41(c)(3) would be incorporated into proposed § 416.54(d)(2)(i) and (iv).

We proposed to require ASCs to meet most of the same proposed emergency preparedness requirements as those we proposed for hospitals, with two exceptions. At § 416.54(c)(7), we proposed that ASCs be required to have policies and procedures that include a means of providing information about the ASCs' needs and their ability to provide assistance (such as physical space and medical supplies) to the authority having jurisdiction (local, state agencies) or the Incident Command Center, or designee. However, we did not propose that these facilities provide information regarding their occupancy, as we proposed for hospitals, since the term "occupancy" usually refers to occupancy in an inpatient facility. Additionally, we did not propose that these facilities provide for subsistence needs of their patients and staff.

Comment: Many commenters commended CMS' efforts to ensure that providers are prepared for emergencies. However, these commenters disagreed with CMS' proposed emergency preparedness requirements for ASCs. The commenters stated that the proposed requirements are too burdensome and that the current ASC disaster preparedness requirements in § 416.41(c) allow providers the appropriate amount of flexibility during an emergency. The commenters stated that ASCs should not be subjected to the same emergency preparedness requirements as hospitals. Most of these commenters requested that CMS revise the proposed emergency preparedness requirements for ASC. Some of these commenters recommended that CMS not finalize any of the proposed emergency preparedness requirements for ASCs.

Response: We understand the commenter's concerns and we agree with some of the comments that suggested that the emergency preparedness requirements for ASC should be modified, and we discuss these modifications in this rule. However, we disagree with the commenter's statement that emergency preparedness requirements for ASCs are burdensome and inflexible. We continue to believe that ASCs should develop an emergency preparedness plan that is based on a facility-based and community-based risk assessment utilizing an all-hazards approach. We believe that the emergency preparedness requirements finalized in this rule provide ASCs and other providers with the flexibility to develop a plan that is tailored to the specific needs of an individual ASC. There are several key differences between the requirements for ASCs and hospitals, including but not limited to subsistence needs requirements and the requirements to implement an emergency and standby power system. We have taken into consideration the unique characteristics of an ASC and have finalized flexible and appropriate emergency preparedness requirements for ASCs.

Comment: Several commenters agreed with exempting ASCs from the requirements to provide occupancy information and subsistence needs for staff and patients. The commenters noted that these requirements would be inappropriate for the ASC setting since many patients may visit an ASC once or twice during an episode of care. However, the commenters noted that other emergency preparedness requirements are inappropriate for the ASC setting. The commenters expressed concern about the requirement that ASCs must develop an emergency preparedness plan that includes a process for ensuring cooperation and collaboration with local, tribal, regional, state, and federal emergency preparedness official's efforts to ensure an integrated response during a disaster or emergency situation. The commenters noted that in many instances, communities do not include ASCs in their emergency preparedness efforts. They recommended that CMS explicitly state that an ASC is in compliance with all community-based requirements, as long as the ASC has written documentation of its attempts to cooperate and collaborate with community organizations, even if the community organizations never respond.

Response: We appreciate the commenter's support. Based on responses from several commenters, we are changing the wording of § 416.54(a) for this final rule to state that ASCs must include a process for maintaining cooperation and collaboration with local, tribal, regional, state, and federal emergency preparedness officials' efforts to ensure an integrated response during a disaster or emergency situation. We expect that ASCs will document their efforts to contact pertinent emergency preparedness officials and, when applicable, document their participation in any collaborative and cooperative planning efforts. We understand that providers cannot control the actions of other entities within their community and we are not expecting providers to hold others accountable for their participation or lack of participation in community emergency preparedness efforts. However, providers do have control over their own efforts and can develop a plan to cooperate and collaborate with members of the emergency preparedness community. We continue to believe that communication and cooperation with pertinent emergency preparedness officials is an important part of a coordinated and timely response to an emergency.

Comment: Several commenters expressed concern about the proposal to require that ASCs develop arrangements with other ASCs and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to ASC patients. The commenters noted that many ASCs offer specific, specialized elective procedures and non-emergency services and that the staff that work in an ASC do not have experience with trauma surgery and triaging. They also noted that, in case of an emergency, ASCs would cancel upcoming procedures, stabilize patients already in the facility, transfer patients who require a higher level of care, account for all ASC staff and volunteers, and either shelter in place current staff and volunteers or send them home. The commenters requested that CMS not finalize this proposal.

Response: We agree with the commenters. We understand that most ASCs are highly specialized facilities that would not necessarily transfer patients to other ASCs during an emergency and, based on this understanding of the nature of ASCs, we believe that ASCs should not be required to establish arrangements with other ASCs to transfer and receive patients during an emergency. Therefore, we are not finalizing the proposed requirement at § 416.54(b)(6). During an emergency, if a patient requires care that is beyond the capabilities of the ASC, we would expect that ASCs would transfer patients to a hospital with which the ASC has a written transfer agreement, as required by existing § 416.41(b), or to the local hospital, that meets the requirements of § 416.41(b)(2), where the ASC physicians have admitting privileges. ASCs should also consider in, their risk assessment, alternative hospitals outside of the area to transfer patients to, if the hospital with which the ASC has a written transfer agreement or admitting privileges is also affected by the emergency.

Comment: A commenter stated that the proposed rule was unclear about what is expected of ASCs in regards to requirements for alternate sources of energy to maintain temperature, emergency lighting, and fire detection, extinguishing and alarm systems.

Response: We did not propose specific temperature, emergency lighting, fire detection, extinguishing and alarm systems, or emergency and standby power requirements for ASCs. However, ASCs would be expected to follow all pertinent federal, state, and local law requirements outside of these regulations.

Comment: A commenter was concerned that ASCs would be required to comply with the Emergency Preparedness Checklist: Recommended Tool for Effective Health Care Facility Planning, before the final emergency preparedness regulations are published. The commenter suggested that the current survey process could be used to collect statistically significant data regarding the application of the final rule.

Response: The emergency preparedness checklist that the commenter refers to is a recommended checklist for emergency preparedness only. We are not requiring ASCs or other providers to comply with the recommendations in this checklist. However, ASCs must comply with the emergency preparedness requirements finalized in this rule 1 year after the final rule is published, as discussed in section II.B. of this final rule.

Comment: We proposed to require ASCs to track their patients and staff before and during an emergency. Most commenters questioned why some of the outpatient suppliers, such as CORFs and Organizations, were being treated differently and not required to track their patients and staff during an emergency when their services were vital to their patient populations. Commenters indicated that similar to these facilities, ASCs also have the flexibility to cancel appointments and close in the event of an emergency. Commenters requested that we remove this requirement.

Response: We proposed this requirement for ASCs because we believed an ASC should maintain responsibility for their staff and patients, if staff and patients were in the facility during the event of an emergency. For reasons discussed earlier, we have removed ''after the emergency'' from the regulations text for ASCs. We agree that if an emergency were to arise, ASCs would have the flexibility to cancel appointments and close. However, we also believe that emergencies may arise while staff and patients are in the ASC. Therefore, we do not believe the requirement should be removed. Instead, we are revising the regulations text further to require that if any staff or patients are in the ASC during an emergency and transferred elsewhere for continued or additional care, the ASC must document the specific name and location of the receiving facility or other location for those patients and on-duty staff who are relocated during and emergency. We note that if the ASC is able to close or cancel appointments, there would be no need to track patients or staff.

Comment: Several commenters expressed concern about whether the communication requirement could be interpreted to require the use of EHRs in ASCs. They noted that ASCs have not been included in recent federal programs that foster the use of healthcare information technology. A commenter noted that almost no ASCs are equipped with an interoperable EHR system that could communicate with other providers and suppliers.

Response: As finalized, § 416.54(c)(4) requires that facilities have a method for sharing information and medical documentation for patients under the ASC's care, as necessary, with other healthcare facilities to ensure continuity of care. We are not requiring, nor are we endorsing, a specific digital storage device or technology for sharing information and medical documentation. Furthermore, we are not requiring facilities to use EHRs or other methods of electronic storage and dissemination. In this regard, we acknowledge that some facilities are still using paper based documentation. However, we encourage all facilities to investigate effective ways to secure, store, and disseminate medical documentation, as permitted by the HIPAA Privacy Rule, to ensure continuity of care during an emergency or a disaster.

Comment: A few commenters stated that the proposed communication plan requirements would unnecessarily overburden ASCs. A commenter indicated specific concerns about ASCs maintaining contact information for other ASCs and stated that since ASCs are not 24-hour care facilities and because a transfer to another facility would likely be the result of a patient needing a high level of care, it is not reasonable for an ASC to have the contact information for other ASCs in their communication plan. Furthermore, the commenter noted that it is unreasonable for ASCs to have contact information for a list of emergency volunteers.

Other commenters stated that it would be reasonable for an ASC to develop a communication plan that would require ASCs to maintain contact information for those who work at their facilities and for community emergency preparedness staff.

Response: We disagree with the commenter's suggestion that ASCs would not be able to develop a communication plan that would include policies to maintain the contact information of the appropriate facility and emergency preparedness staff. ASCs are one of the few provider and supplier types that already have CfCs for emergency and disaster preparedness. They are currently required to maintain a written disaster preparedness plan that provides for care of patients and staff during an emergency and to coordinate the plan with state and local authorities, as appropriate. Therefore, we would expect that these ASC facilities would already have contact information for emergency management authorities and appropriate staff. We believe that, in light of these existing requirements, it is feasible for an ASC to continue to maintain these requirements and include written documentation for a communication plan.

However, we do agree with the commenters that it may be unreasonable for an ASC to maintain the contact information for other ASCs, given the highly specialized nature of care in most ASC facilities. The procedures performed in an ASC vary depending on the focus of the ASC. Some ASCs specialize solely in eye procedures, while other may specialize in orthopedics, plastic surgery, pain treatment, dental, podiatric, urological, etc. Therefore, we are not finalizing our proposal to require that ASCs maintain the names and contact information for other ASCs in the ASC's communication plan.

Comment: Several commenters addressed the proposal that would require ASCs to release patient information as permitted under 45 CFR 164.510 of the HIPAA Privacy Rule and to have a communication system in place capable of generating timely, accurate information that could be disseminated, as permitted, to family members and others. The commenters stated that this proposal is inappropriate for the ASC setting. The commenters noted that ASCs should be exempt from this requirement, since ASCs do not provide continuous care to patients nor to patients who are homebound or receiving services at home.

Response: We disagree with the commenters' statement that ASCs should be exempt from the proposed requirement at § 416.54(c)(6) that ASCs establish in their communication plan a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510. While it is true that ASCs do not provide continuous care to patients, we believe it is still of utmost importance for ASCs to be prepared to disseminate information about a patient's status, should an unforeseen emergency occur while the ASC is open and in operation. We believe that ASCs are fully capable of establishing an effective communication plan that would allow for the release of patient information in the event of an evacuation. Also, we believe that ASCs should be prepared to disseminate information on patients under the ASC's' care to family members during an emergency, as permitted under 45 CFR 164.510(b)(1)(ii). Therefore, it is important that ASCs have a plan in advance of this type of situation that would entail how the ASC would coordinate this effort to provide patient information. For example, if a patient is undergoing a procedure in an ASC and, due to an unforeseen natural disaster, the ASC is forced to evacuate or shelter in place, the ASC should have a system in place should they need to use or disclose protected health information to notify, or assist in the notification of, a family member, a personal representative, or another person responsible for the care of the patient of the patient's location, general health condition, or death. We believe patients would be ill-served, and ASCs would be unprepared, if such a situation were to occur without a communication plan that establishes means, in the event of an evacuation, to release patient information. We note that the requirements of this final rule allow ASCs flexibility to construct a communication plan that best serves the facility's and their patients' individual circumstances.

Comment: We received several comments from the ASC community that opposed our proposal to require ASCs to participate in a community mock disaster drill at least once a year. The majority of the commenters noted that ASCs are not included in emergency preparedness efforts of their community. A commenter specifically noted that many communities do not include ASCs in their emergency preparedness efforts because they are primarily outpatient facilities that provide elective surgery, and are not designed to accommodate an influx of patients in case of an emergency. Another commenter noted that the proposed rule does allow for ASCs to conduct a facility-based disaster drill if a community drill is not available; however they stated that a drill of any kind would likely impose an additional burden on an ASC due to limited staff. A commenter suggested that ASCs be allowed to conduct a facility-based disaster drill if a community drill is not available or if the ASC is not part of a community's emergency preparedness efforts.

Response: We recognize the existence of a lack of community collaboration in some areas as it relates to emergency preparedness, which is one of the reasons we are seeking to establish unified emergency preparedness standards for all Medicare and Medicaid providers and suppliers. As noted earlier, we stated in the proposed rule that if a community disaster drill is not available, we would require an ASC to conduct an individual facility-based disaster drill. We also note that for the second annual testing requirement we are revising our testing standards to allow either a community disaster drill or a tabletop exercise annually, so an ASC may opt to conduct a tabletop exercise over a facility-based drill.

After consideration of the comments we received on the proposed emergency preparedness requirements for ASCs and the general comments we received on the proposed rule, as discussed in the hospital section (section II.C. of this final rule), we are finalizing the proposed emergency preparedness requirements for ASCs with the following modifications:

- Revising the introductory text of § 416.54 by adding the term "local" to clarify that ASCs must also comply with local emergency preparedness requirements.
- Revising § 416.54(a)(4) to delete the term "ensuring" and to replace the term "ensure" with "maintain."
- Revising § 416.54(b)(1) to remove the requirement for ASCs to track all staff and patients after an emergency and requiring that if any on-duty staff or patients are in the ASC during an emergency and transferred or relocated, the ASC must document the specific name and location of the receiving facility or other location.
- Revising § 416.54(b)(4)(iii) by replacing the phrase "ensures records are secure" with the phrase "secures and maintains the availability of records."
- Removing § 416.54(b)(6) that requires that ASCs develop arrangements with other ASCs and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to ASC patients, and renumbering paragraph (b)(7) as paragraph (b)(6).
- Revising § 416.54(c) by adding the term "local" to clarify that the ASC must develop and maintain an emergency preparedness communication plan that also complies with local laws.
- Revising § 416.54(c)(1)(iv) to remove the requirement that ASCs include the names and contact information for "Other ASCs" in the communication plan.
- Revising § 416.54(c)(5) to clarify that ASCs must develop a means, in the event of an evacuation, to release patient information, as permitted under 45 CFR 164.510(b)(1)(ii).
- Revising § 416.54(d) by adding that each ASC's training and testing program must be based on the ASC's emergency plan, risk assessment, policies and procedures, and communication plan.
- Revising § 416.54(d)(1)(iv) by replacing the phrase "ensure that staff can" with the phrase "demonstrate staff."
- Revising § 416.54(d)(2)(i) by removing the requirement for ASCs to participate in a community-based disaster drill.
- Revising § 416.54(d)(2) to allow an ASC to choose the type of exercise they will conduct to meet the second annual testing requirement.
- Adding § 416.54(e) to allow a separately certified ASC within a healthcare system to elect to be a part of the healthcare system's emergency preparedness program.

F. Emergency Preparedness Regulations for Hospices (§ 418.113)

Section 122 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), Public Law 97–248, added section 1861(dd) to the Act to provide coverage for hospice care to terminally ill Medicare beneficiaries who elect to receive care from a Medicare-participating hospice. Under the authority of section 1861(dd) of the Act, the Secretary has established the CoPs that a hospice must meet in order to participate in Medicare and Medicaid The CoPs found at part 418, subparts C and D, apply to a hospice, as well as to the services furnished to each patient under hospice care.

Hospices provide palliative care rather than traditional medical care and curative treatment to terminally ill patients. Palliative care improves the quality of life of patients and their families facing the problems associated with terminal illness through the prevention and relief of suffering by means of early identification, assessment, and treatment of pain and other issues.

As of June 2016, there were 412 inpatient hospice facilities nationally. Under the existing hospice CoPs, hospice inpatient facilities are required to have a written disaster preparedness plan that is periodically rehearsed with hospice employees, with procedures to be followed in the event of an internal or external disaster and procedures for the care of casualties (patients and staff) arising from such disasters. This requirement, which is limited in scope, is found at § 418.110(c)(1)(ii) under "Standard: Physical environment."

For hospices, we proposed to retain existing regulations at § 418.110(c)(1)(i), which state that a hospice must address real or potential threats to the health and safety of the patients, other persons, and property. However, we proposed to incorporate the existing requirements at § 418.110(c)(1)(ii) into proposed § 418.113(a)(2) and (d)(1). We proposed to require at § 418.113(a)(2) that the hospice's emergency preparedness plan include contingencies for managing the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care. In addition, we proposed to require at § 418.113(d)(1)(iv) that the hospice periodically review and rehearse its emergency preparedness plan with hospice employees with special emphasis placed on carrying out the procedures necessary to protect patients and others. We proposed that § 418.110(c)(1)(ii) and the designation for paragraph (i) of § 418.110(c)(1) be removed. Otherwise, the proposed emergency preparedness requirements for hospice providers were very similar to those for hospitals.

In the proposed rule, we stated that despite the key differences between hospitals and hospices, we believed the hospital emergency preparedness requirements, with some reorganization and revision are appropriate for hospice providers. Thus, our discussion focused on the requirements as they differed from the requirements for hospitals within the context of the hospice setting. Since hospices serve patients in both the community and within various types of facilities, we proposed to organize the requirements for the hospice provider's policies and procedures differently from the proposed policies and procedures for hospitals. Specifically, we proposed to group requirements that apply to all hospice providers at § 418.113(b)(1) through (5) followed by requirements at § 418.113(b)(6) that apply only to hospice inpatient care facilities.

Unlike our proposed hospital policies and procedures, we proposed at § 418.113(b)(2) to require all hospices, regardless of whether they operate their own inpatient facilities, to have policies and procedures to inform state and local officials about hospice patients in need of evacuation from their respective residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment. Such policies and procedures must be in accord with the HIPAA Privacy Rule, as appropriate. This proposed requirement recognized that many frail hospice patients may be unable to evacuate from their homes without assistance during an emergency. This additional proposed requirement recognized the responsibility of the hospice to support the safety of its patients that reside in the community.

We note that the proposed requirements for communication at § 418.113(c) were the same as for hospitals, with the exception of proposed § 418.113(c)(7). At § 418.113(c)(7), for hospice facilities, we proposed to limit to inpatients the requirement that the hospice have policies and procedures that would include a means of providing information about the hospice's occupancy and needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee. The proposed requirements for training and testing at § 418.113(d) were the same as those proposed for hospitals.

Comment: A commenter stated that it was unreasonable for home based hospices to be aligned with or have similar emergency preparedness requirements as hospitals. Another commenter requested that we exempt inpatient hospice facilities from meeting the same emergency standards as hospitals.

Response: We understand that residential facilities function much differently than hospitals; however we do not believe that we solely aligned the hospice requirements with hospitals. As stated in the proposed rule, we proposed to develop core components of emergency preparedness that could be used across provider and supplier types, while tailoring requirements for individual provider and supplier types to their specific needs and circumstances, as well as the needs of their patients. Specifically for hospice providers, we believe that we gave much consideration to whether the hospice was home based or an inpatient hospice. For example, we organized the hospice policies and procedures requirements based on those that apply to all hospice providers and those that apply to only hospice inpatient care facilities. Given the terminally ill status of hospice patients, we continue to believe that in an emergency situation they may be as or more vulnerable than their hospital counterparts. This could be due to the inherent severity of the hospice patient's illness or to the probability that the hospice patient's caregiver may not have the level of professional expertise, supplies, or equipment of the hospital-based clinician. We continue to believe that the hospital emergency requirement, with some reorganization and revision as proposed, is appropriate for all hospice providers. In addition, we note that existing hospice regulations at § 418.110(c)(1) already require inpatient hospice facilities to have a written disaster preparedness plan. Therefore, we do not agree that an exemption for inpatient or outpatient hospice facilities is appropriate.

Comment: A commenter noted that inpatient hospice facilities are often small in size and free-standing rather than integrated into larger healthcare facilities. The commenter requested that we provide flexibility in our requirements based on the size of a facility. In addition, the commenter indicated that smaller inpatient hospices do not have institutional kitchens and often contract for the provision of food. The commenter questioned whether it is acceptable to provide readymade meals for patients and staff for sheltering in place and for what period of time will hospices be expected to prepare to provide subsistence needs.

Response: We appreciate the commenter's feedback. Where feasible, we did not propose overly prescriptive requirements for any of the providers and suppliers, regardless of size. We note that we are only requiring facilities to have policies and procedures to address the provision of subsistence in the event of an emergency. This could include establishing a relationship with a non-profit that provides meals during disasters. All hospices have the flexibility to determine and manage the types, amounts, and needed preparation for providing subsistence needs based on their own facility risk assessments. We believe that allowing each individual hospice the flexibility to identify the subsistence needs that would be required during an emergency is the most effective way to address subsistence needs without imposing undue burden.

Comment: A commenter recommended that the executive team of each individual hospice should determine which staff should participate in the creation of their emergency preparedness plans, process, and tools.

Response: We thank the commenter for their suggestion. We did not indicate who must develop the emergency preparedness plans. All providers and suppliers have the flexibility to determine the appropriate staff that should be involved in the development of their entire emergency preparedness program.

Comment: A commenter supported our requirement for hospices to develop procedures to inform State and local officials about hospice patients in need of evacuation from their residences due to an emergency situation. However, the commenter indicated that for smaller hospice providers, developing and maintaining a current list of patients in need of evacuation assistance, along with the type of assistance required, will be a time-consuming manual effort. The commenter requested that we provide as much flexibility to this requirement as possible.

Response: We appreciate the commenter's support and feedback. We disagree with the statement that it would be overly burdensome for hospices to maintain a current list of patients and their needs of assistance. We also note that we did not limit the way in which hospices have to collect, maintain, or share this information. As a best practice, most hospices, regardless of size, maintain an up-to-date list of their current patients for organizational purposes and to maintain operations. In addition, we believe that it is current practice for staff to make daily assessments of the needs and capabilities of their hospice patients. We would also assume that the smaller the hospice, the smaller the number of patients they would need to assess and document. We continue to believe that it is critically important that hospices have a way to share this information with State and local officials.

Comment: Specific to hospices, commenters were unclear about what it would mean for a hospice to track patients from setting to setting during an emergency. For those home-based hospices, commenters noted that unlike an institutional setting, hospice patients reside in the community and their private residence with access to travel freely. Commenters supported the intent of the requirement, but requested that CMS revise this requirement taking into consideration the complexity of tracking patients receiving home-based care.

Response: We understand that we were not clear in our proposal about our intentions as to how hospice providers could meet this requirement. In addition, after reviewing the issues raised by commenters, we agree that further consideration should be given to variations between inpatient hospices and home based hospices. We agree that this factor, whether the hospice is inpatient or home based, creates a difference in the hospice provider's ability to track patients. Therefore, we are removing the requirement for home based hospices to track their staff and patients. Similar to the revisions we made for HHA, we are replacing the tracking requirement with a requirement for home based hospices to have policies and procedures that address the follow up procedures the hospice will exercise in the event that their services are interrupted during or due to an emergency event. In addition, the hospice must inform state and local officials of any on-duty staff or patients that they are unable to contact. Similar to the revisions we made for hospitals, we are keeping the requirement for inpatient hospices to track staff and patients during an emergency, but removing the language "after the emergency" from the regulation text. Instead we are revising the text to clarify that in the event that on-duty staff or patients are relocated during an emergency, the inpatient hospice must document the specific name and location of the receiving facility or other location for on-duty staff and patients who leave the facility during the emergency (that is, another facility, alternate sheltering location, etc.). We expect that for administrative purposes, all hospices already have some mechanism in place to keep track of patients and staff contact information. In addition, we expect that as a best practice, all hospices will find it necessary to communicate and follow up with their patients during or after an interruption in their services to close the loop on what services are needed and can still be provided. All hospices will have the flexibility to determine how best to develop these procedures, whether they utilize an electronic communication or some other method. We expect that the information would be readily available, accurate, and shareable among officials within and across the emergency response system, as needed, in the interest of the patient.

Comment: A hospice provider agreed with the need for a communication plan to be included in the emergency plan, but was unsure whether this should be addressed in a separate regulation specifically addressing communication. Another commenter supported the proposed communication plan requirements for hospices and HHAs, and noted the importance of communicating information to relevant authorities and facilities about the location and condition of vulnerable individuals, who may have difficulty evacuating during a disaster or emergency due to the severity of their illness.

Response: We appreciate the commenters' support and we agree with the commenters' point about the importance of communicating patient information, especially for vulnerable populations. We believe that it is important that hospice providers include in their emergency preparedness plans a communication plan that is reviewed and updated annually. We believe that requirements for a hospice's communication plan should be included in these emergency preparedness regulations, since we believe that an emergency preparedness plan for facilities is not complete without plans for communicating during an emergency or disaster.

Comment: A few hospice providers expressed concern about the proposed communication plan for hospices with respect to federal and state funding and support.

A commenter stated that most hospices do not have access to funding to purchase communication networks that link to first responders, hospitals, and county/regional Incident Command Centers. They stated that, aside from land lines and cell phones if they are available, communication could be very challenging, if not impossible. Another commenter stated that it would take more time, and more federal and state support, for hospice providers to meet the proposed requirements.

Response: We thank the commenters for their feedback. We understand the commenters' concerns about means of communication for hospice providers and refer readers to various communication planning resources, including *http://www.hhs.gov/ocio/ea/National%20Communication%20System/* (The National Communication System) and those resources referenced in the proposed rule and this final rule.

We expect facilities to develop and maintain policies and procedures for patient care and their overall operations.

The emergency preparedness requirement may increase costs in the short term because resources would have to be devoted to the assessment and development of an emergency plan that utilizes an all-hazards approach. While the proposed requirements could result in some immediate costs to a provider or supplier, we believe that developing an emergency preparedness program would be beneficial overall to any provider or supplier. In addition, we believe that planning for the protection and care of patients, clients, residents, and staff during an emergency or a disaster is a good business practice.

Comment: A few commenters expressed their concern about our proposal to require hospices to participate in both a community mock disaster drill and a paper based tabletop exercise. Mainly, the commenters acknowledged the benefits and necessity of participating in drills and exercises to determine the effectiveness of an emergency plan, but stated that conducting drills and exercises in the hospice setting is time consuming and would disrupt and compromise patient care.

Response: We agree that patient care is always the priority; however we believe that requiring staff to participate in training once a year is reasonable. Since the training will be anticipated, we believe that it would be possible for staff to work with their patients to adjust their schedules accordingly in order to participate in any such training. Emergency preparedness testing and training could be consolidated with other hospice training to reduce the impact and address staffing limitations. In addition, we believe that our decision to change our proposal to allow for either a community disaster drill or a tabletop exercise annually for the second annual testing requirement will provide hospices with the flexibility to determine which testing drill or exercise would be most beneficial to their organization, taking into consideration factors such as staff limitations and financial cost.

After consideration of the comments we received on the proposed emergency preparedness requirements for hospices, and the general comments we received on the proposed rule, as discussed in the hospital section (section II.C. of this final rule), we are finalizing the proposed emergency preparedness requirements for hospices with the following modifications:

- Revising the introductory text of § 418.113 by adding the term "local" to clarify that hospices must also coordinate with local emergency preparedness requirements.
- Revising § 418.113(a)(4) to delete the term "ensuring" and to replace the term "ensure" with "maintain."
- Revising § 418.113(b)(1) to remove the requirement for home-based hospices to track staff and patients.
- Revising 418.113(b)(1) to clarify that in the event that there is an interruption in services during or due to an emergency, home based hospices must have policies in place for following up with on-duty staff and patients to determine services that are still needed. In addition, they must inform State and local officials of any on-duty staff or patients that they are unable to contact.
- Revising § 418.113(b)(5) to delete the term "ensure" and to replace it with the term "maintain."
- Revising § 418.113(b)(6)(iii)(A) by adding that hospices must have policies and procedures that address the need to sustain pharmaceuticals during an emergency.
- Revising § 418.113(b)(6) by adding a new paragraph (v) to require that inpatient hospices track on-duty staff and patients during an emergency, and, in the event staff or patients are relocated, inpatient hospices must document the specific name and location of the receiving facility or other location to which on-duty staff and patients were relocated to during the emergency.
- Revising § 418.113(c) by adding the term "local" to clarify that the hospice must develop and maintain an emergency preparedness communication plan that also complies with local laws.
- Revising § 418.113(c)(5) to clarify that hospices must develop a means, in the event of an evacuation, to release patient information, as permitted under 45 CFR 164.510(b)(1)(ii).
- Revising § 418.113(d) by adding that each hospice's training and testing program must be based on the hospice's emergency plan, risk assessment, policies and procedures, and communication plan.
- Revising § 418.113(d)(1)(ii) to replace the phrase "Ensure that hospice employees can demonstrate" to "Demonstrate staff."
- Revising § 418.113(d)(2)(i) by replacing the term "community mock disaster drill" with "full-scale exercise."
- Revising § 418.113(d)(2) to allow a hospice to choose the type of exercise it will conduct to meet the second annual testing requirement.
- Adding § 418.113(e) to allow separately certified hospices within a healthcare system to elect to be a part of the healthcare system's emergency preparedness program.

G. Emergency Preparedness Regulations for Psychiatric Residential Treatment Facilities (PRTFs) (§ 441.184)

Sections 1905(a)(16) and (h) of the Act define the term "Psychiatric Residential Treatment Facility" (PRTF) and list the requirements that a PRTF must meet to be eligible for Medicaid participation. To qualify for Medicaid participation, a PRTF must be certified and comply with conditions of payment and CoPs, at §§ 441.150 through 441.182 and §§ 483.350 through 483.376 respectively. As of June 2016, there were 377 PRTFs.

A PRTF provides inpatient psychiatric services for patients under age 21. Under Medicaid, these services must be provided under the direction of a physician. Inpatient psychiatric services must involve active treatment which means implementation of a professionally developed and supervised individual plan of care. The patient's plan of care includes an integrated program of therapies, activities, and experiences designed to meet individual treatment objectives that have been developed by a team of professionals along with the patient, his or her parents, legal guardians, or others into whose care the patient will be released after discharge. The plan must also include post-discharge plans and coordination with community resources to ensure continued services for the patient, his or her family, school, and community.

The current PRTF requirements do not include any requirements for emergency preparedness. We proposed to require that PRTF facilities meet the same requirements we proposed for hospitals. Because these facilities vary widely in size, we would expect that their emergency preparedness risk assessments, emergency plans, policies and procedures, communication plan, and training and testing will vary widely as well. However, we believe PRTFs have the capability to comply fully with emergency preparedness requirements so that the health and safety of its patients are protected in the event of an emergency situation or disaster.

Comment: A commenter questioned if a generator would be required to be used as an alternate source of energy.

Response: Emergency and standby power systems are not a requirement for PRTFs. That requirement applies only to hospitals, CAHs and LTC facilities. Alternate sources of energy could include, for example, propane, gas, and water-generated systems, in addition to other resources.

Comment: A commenter stated that it would be difficult for PRTFs, ICFs/IIDs, and CMHCs to implement a method to share patient information and medical documentation with other healthcare facilities to ensure continuity of care, since these entities are not uniformly using electronic health records. Therefore, the commenter recommended flexibility in the implementation of these requirements.

The commenter also noted that the CMS proposed rule stated that PRTFs are not likely to have formal communication plans. However, the commenter stated that PRTFs accredited by TJC are subject to Standard EM.02.02.01, which requires that the organization include in an emergency preparedness plan details on how the facility will communicate during emergencies.

Response: We believe that we have allowed for flexibility in how PRTFs develop and maintain their communication plans. However, if the commenter is referring to flexibility in when these requirements will be implemented, we refer the commenter to the section of this final rule that implements an effective date that is 1 year after the effective date of this final rule for these emergency preparedness requirements for all providers and suppliers.

In addition, we acknowledge that some PRTFs may already have communication plans in place, as required as a condition of TJC accreditation. We appreciate the commenter's feedback and note that facilities that meet TJC accreditation standards should be well-equipped to comply with the communication plan requirements established in these CoPs.

Comment: In response to our proposed requirement for a PRTF to participate in a community disaster drill, we received one comment which stated that PRTFs are often not included in their larger community's preparedness plan. The commenter stated that the lack of inclusion often occurs despite the willingness and request on the part of the PRTF. The commenter recommended that we allow documentation of best efforts to be a part of the community disaster drill to meet this requirement.

Response: We recognize the existence of a lack of community collaboration in some areas as it relates to emergency preparedness, which is one of the reasons why we are seeking to establish unified emergency preparedness standards for Medicare and Medicaid providers and suppliers. We stated in the proposed rule that if a community disaster drill is not available, we would require a PRTF to conduct an individual facility-based disaster drill/full-scale exercise. A PRTF is expected to document its efforts to participate in a community disaster drill; however, the requirement to conduct a facility-based disaster drill/full-scale exercise would still need to be met.

After consideration of the comments we received on the proposed emergency preparedness requirements for PRTFs, and the general comments we received on the proposed rule in the hospital section (section II.C. of this final rule), we are finalizing the proposed emergency preparedness requirements for PRTFs with the following modifications:

- Revising the introductory text of § 441.184 by adding the term "local" to clarify that PRTFs must also comply with local emergency preparedness requirements.
- Revising § 441.184(a)(4) to delete the term "ensuring" and to replace the term "ensure" with "maintain."
- Revising § 441.184(b)(1)(i) by adding that PRTFs must have policies and procedures that address the need to sustain pharmaceuticals during an emergency.
- Revising § 441.184(b)(2) by clarifying that tracking during and after the emergency applies to on-duty staff and sheltered residents. We have also revised paragraph (b)(2) to provide that if on-duty staff and sheltered residents are relocated during the emergency, the facility must document the specific name and location of the receiving facility or other location.
- Revising § 441.184(b)(5) to change the phrase "ensures records are secure and readily available" to "secures and maintain availability of records."
- Revising § 441.184(b)(7) to replace the term "ensure" with "maintain."
- Revising § 441.184(c) by adding the term "local" to clarify that the PRTF must develop and maintain an emergency preparedness communication plan that also complies with local laws.
- Revising § 441.184(c)(5) to clarify that PRTFs must develop a means, in the event of an evacuation, to release patient information, as permitted under 45 CFR 164.510(b)(1)(ii).
- Revising § 441.184(d) by adding that each PRTF's training and testing program must be based on the PRTF's emergency plan, risk assessment, policies and procedures, and communication plan.
- Revising § 441.184(d)(1)(iii) to replace the phrase "ensure that staff can demonstrate" to "Demonstrate staff knowledge."
- Revising § 441.184(d)(2)(i) by replacing the term "community mock disaster drill" with "full-scale exercise."
- Revising § 441.184(d)(2)(ii) to allow a PRTF to choose the type of exercise it will conduct to meet the second annual testing requirement.
- Adding § 441.184(e) to allow a separately certified PRTF within a healthcare system to elect to be a part of the healthcare system's emergency preparedness program.

H. Emergency Preparedness Regulations for Programs of All-Inclusive Care for the Elderly (PACE) (§ 460.84)

The Balanced Budget Act (BBA) of 1997 established the Program of All-Inclusive Care for the Elderly (PACE) as a permanent Medicare and Medicaid provider type. Under sections 1894 and 1934 of the Act, a state participating in PACE must have a program agreement with CMS and a PACE organization. Regulations at § 460.2 describe the statutory authority that permits entities to establish and operate PACE programs under section 1894 and 1934 of the Act and § 460.6 defines a PACE organization as an entity that has in effect a PACE program agreement. Sections 1894(a)(3) and 1934(a)(3) of the Act define a "PACE provider." The PACE model of care includes the provision of adult day healthcare and interdisciplinary team care management as core services. Medical, therapeutic, ancillary, and social support services are furnished in the patient's residence or on-site at a PACE center. Hospital, nursing home, home health, and other specialized services are furnished under contract. A PACE organization provides medical and other support services to patients predominantly in a PACE adult day care center. As of June 2016, there are 119 PACE programs nationally.

Regulations for PACE organizations at part 460, subparts E through H, set out the minimum health and safety standards a facility must meet in order to obtain Medicare certification. The current CoPs for PACE organizations include some requirements for emergency preparedness. We proposed to remove the current PACE organization requirements at § 460.72(c)(1) through (5) and incorporate these existing requirements into proposed § 460.84, Emergency preparedness requirements for Programs of All-Inclusive Care for the Elderly (PACE).

Currently § 460.72(c)(1), Emergency and disaster preparedness procedures, states that the PACE organization must establish, implement, and maintain documented procedures to manage medical and nonmedical emergencies and disasters that are likely to threaten the health or safety of the patients, staff, or the public. Currently § 460.72(c)(2) defines emergencies to include, but not be limited to: Fire; equipment, water, or power failure; care-related emergencies; and natural disasters likely to occur in the organization's geographic area.

We proposed incorporating the language from § 460.72(c)(1) into § 460.84(b). Existing § 460.72(c)(2), which defines various emergencies, would be incorporated into § 460.84(b) as well. We did not add the statement in current § 460.72(c)(2), that "an organization is not required to develop emergency plans for natural disasters that typically do not affect its geographic location" because we proposed that PACE organizations utilize an "all-hazards" approach at § 460.84(a)(1).

Existing § 460.72(c)(3), which states that a PACE organization must provide appropriate training and periodic orientation to all staff (employees and contractors) and patients to ensure that staff demonstrate a knowledge of emergency procedures, including informing patients what to do, where to go, and whom to contact in case of an emergency, would be incorporated into proposed § 460.84(d)(1). The existing requirements for having available emergency medical equipment, for having staff who know how to use the equipment, and having a documented plan to obtain emergency medical assistance from outside sources in current § 460.72(c)(4) would be relocated to proposed § 460.84(b)(9). Finally, current § 460.72(c)(5), which states that the PACE organization must test the emergency and disaster plan at least annually and evaluate and document its effectiveness would be addressed by proposed § 460.84(d)(2). The current version of § 460.72(c)(1) through (5) would be removed.

We proposed that PACE organizations adhere to the same requirements for emergency preparedness as hospitals, with three exceptions. We did not propose that PACE organizations provide for basic subsistence needs of staff and patients, whether they evacuate or shelter in place, including food, water, and medical supplies; alternate sources of energy to maintain temperatures to protect patient health and safety and for the safe and sanitary storage of provisions; emergency lighting; and fire detection, extinguishing, and alarm systems; and sewage and waste disposal as we proposed for hospitals at § 482.15(b)(1). The second difference between the proposed hospital emergency preparedness requirements and the proposed PACE emergency preparedness requirements was that we proposed adding at § 460.84(b)(4) a requirement for a PACE organization to have policies and procedures to inform state and local officials at any time about PACE patients in need of evacuation from their residences due to an emergency situation, based on the patient's medical and psychiatric conditions and home environment. Such policies and procedures must be in accord with the HIPAA Privacy Rule, as appropriate.

Finally, the third difference between the proposed requirements for hospitals and the proposed requirements for PACE organizations was that, at § 460.84(c)(7), we proposed to require these organizations to have a communication plan that includes a means of providing information about their needs and their ability to provide assistance to the authority having jurisdiction or the Incident Command Center, or designee. We did not propose requiring these organizations to provide information regarding their occupancy, as we proposed for hospitals (§ 482.15(c)(7)), since the term "occupancy" refers to occupancy in an inpatient facility.

Comment: Several commenters, including PACE providers, opposed our proposal to require PACE organizations to provide for the subsistence needs of staff and participants whether they evacuated or sheltered in place during an emergency; while other providers stated that to do so would be a proactive measure to provide provisions for even a short amount of time. Some providers stated that these provisions should be available to this medically vulnerable, at-risk population during an emergency or if shelter in place occurred for a period of time.

Response: We appreciate the variety of responses we received. Based on the comments we received suggesting we include this requirement, we are now adding a requirement that PACE organizations must have policies and procedures in place to address subsistence needs.

Comment: A commenter wanted us to define the term "all-hazards" for PACE organizations. Another commenter requested clarification when facility-based and community-based assessments are assessed at a "zero risk", if this would need to be included in their emergency plan.

Response: The definition of "all-hazards" is discussed under the requirements for hospitals and this definition applies to all provider and supplier types. If there is an assessed zero risk made during the facility and community assessments, then there is no need to include this in their emergency plan.

Comment: A few commenters, including a PACE association and PACE providers, requested further clarification on the requirement that PACE organizations develop and maintain emergency preparedness communication plans that provide "well-coordinated" participant care both within the affected facilities as well as across public health departments and emergency systems. The commenters stated that it would be helpful to have a defined "checklist" by which PACE organizations could determine whether or not they are meeting the requirements to be considered "well-coordinated."

Response: We recognize the importance of this inquiry and suggest that facilities look to the forthcoming interpretive guidelines after the publication of this final rule for more information. We also continue to encourage facilities to seek guidance from the many emergency preparedness resources we have included in the proposed and final rules.

After consideration of the comments we received on the proposed emergency preparedness requirements for PACE organizations, and the general comments we received on the proposed rule, as discussed in the hospital section (section II.C. of this final rule), we are finalizing the proposed emergency preparedness requirements for PACEs with the following modifications:

- Revising the introductory text of § 460.84 by adding the term "local" to clarify that PACE organizations must also coordinate with local emergency preparedness requirements.
- Revising § 460.84(a)(4) to delete the term "ensuring" and to replace the term "ensure" with "maintain."
- Adding § 460.84(b)(1) to address subsistence needs, and renumbering the rest of the section accordingly.
- Revising § 460.84(b)(2) by clarifying that tracking during and after the emergency applies to on-duty staff and sheltered participants. We have also revised paragraph (b)(2) to provide that if on-duty staff and sheltered participants are relocated during the emergency, the facility must document the specific name and location of the receiving facility or other location.
- Revising § 460.84(b)(5) to change the phrase "ensures records are secure and readily available" to "secures and maintains availability of records;" also revising paragraph (b)(7) to change the term "ensure" to "maintain."
- Revising § 460.84(c) by adding the term "local" to clarify that the PACE

organization must develop and maintain an emergency preparedness communication plan that also complies with local laws.

- Revising § 460.84(c)(5) to clarify that the PACE organization must develop a means, in the event of an evacuation, to release patient information, as permitted under 45 CFR 164.510(b)(1)(ii).
- Revising § 460.84(d) by adding that each PACE organization's training and testing program must be based on the PACE organization's emergency plan, risk assessment, policies and procedures, and communication plan.
- Revising § 460.84(d)(1)(iii) to replace the phrase "Ensure that staff can demonstrate knowledge" to "Demonstrate staff knowledge."
- Revising § 460.84(d)(2)(i) by replacing the term "community mock disaster drill" with "full-scale exercise."
- Revising § 460.84(d)(2)(ii) to allow a PACE organization to choose the type of exercise it will conduct to meet the second annual testing requirement.
- Adding § 460.84(e) to allow a separately a certified PACE organization within a healthcare system to elect to be a part of the healthcare system's emergency preparedness program.

I. Emergency Preparedness Regulations for Transplant Centers (§ 482.78)

All transplant centers are located within hospitals. Any hospital that furnishes organ transplants and other medical and surgical specialty services for the care of transplant patients is a transplant hospital (42 CFR 482.70). Therefore, transplant centers must meet all hospital CoPs at §§ 482.1 through 482.57 (as set forth at § 482.68(b)), and the hospitals in which they are located must meet the provisions of § 482.15. The transplant hospital would be responsible for the emergency preparedness program for the entire hospital as set forth in § 482.15, including the transplant center. In addition, unless otherwise specified, heart, heart-lung, intestine, kidney, liver, lung, and pancreas transplant centers must meet all requirements for transplant centers at §§ 482.72 through 482.104.

Transplant centers are responsible for providing organ transplantation services from the time of the potential transplant candidate's initial evaluation through the recipient's post-transplant follow-up care. In addition, if a center performs living donor transplants, the center is responsible for the care of the living donor from the time of the initial evaluation through post-surgical follow-up care.

There are 770 Medicare-approved transplant centers. These centers provide specialized services that are not available at all hospitals. Thus, we believe that it is crucial for every transplant center to work closely with the hospital in which it is located and the designated organ procurement organization (OPO) for that donation service area (DSA) (unless the hospital has a waiver approved by the Secretary to work with another OPO) in preparing for emergencies so that it can continue to provide transplantation and transplantation-related services to its patients during an emergency.

We proposed to add a new transplant center CoP at § 482.78, "Emergency preparedness." Proposed § 482.78(a) would require a transplant center to have an agreement with at least one other Medicare-approved transplant center to provide transplantation services and other care for its patients during an emergency. We also proposed at § 482.78(a) that the agreement between the transplant center and another Medicare-approved transplant center that agreed to provide care during an emergency would have to address, at a minimum: (1) The circumstances under which the agreement would be activated; and (2) the types of services that would be provided during an emergency.

Currently, under the transplant center CoP at § 482.100, Organ procurement, a transplant center is required to ensure that the hospital in which it operates has a written agreement for the receipt of organs with the hospital's designated OPO that identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation. We proposed at § 482.78(b) to require transplant centers to ensure that the written agreement required under § 482.100 also addresses the duties and responsibilities of the hospital and the OPO during an emergency. We included a similar requirement for OPOs at § 486.360(c) in the proposed rule. We anticipated that the transplant center, the hospital in which it is located, and the designated OPO would collaborate in identifying their specific duties and responsibilities during emergency situations and include them in the agreement.

We did not propose to require transplant centers to provide basic subsistence needs for staff and patients, as we are proposing for hospitals at § 482.15(b)(1). Also, we did not propose to require transplant centers to separately comply with the proposed hospital requirement at § 482.15(b)(8) regarding alternate care sites identified by emergency management officials. This requirement would be applicable to inpatient providers since the overnight provision of care could be challenged in an emergency. The hospital in which the transplant center is located would be required under § 482.15 to provide for any transplant patients and living donors that are hospitalized during an emergency.

Comment: Commenters stated that the proposed requirement for transplant centers to have an agreement with at least one other Medicare-approved transplant center to provide transplantation services and related care for its patients during an emergency was unnecessary. They noted that transplant centers have a long history of cooperating with each other during emergencies, such as during Hurricanes Katrina and Rita. A commenter noted that they had never heard of any transplant center that failed to ensure that its patients received appropriate care during an emergency. Many commenters noted that the Organ Procurement and Transplantation Network (OPTN) already has emergency preparedness requirements and that we should rely on the OPTN and the United Network for Organ Sharing (UNOS) to work with transplant centers during emergencies. Specifically, OPTN Policy 1.4.A Regional and National Emergencies, which was effective on September 1, 2014, states that "[d]uring a regional or national emergency, the OPTN contractor will attempt to distribute instructions to all transplant hospitals and OPOs that describe the impact and how to proceed with organ allocation, distribution, and transplantation" (accessed at *http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf#nameddest=Policy_01* on February 24, 2015). Additional policies instruct transplant centers and OPOs to contact the OPTN contractor for instructions when the transportation of organs is either not possible or severely impaired (OPTN Policy 1.4.B), and when communication through the internet or telephone is not possible (OPTN Policies 1.4.C, 1.4.D, and 1.4.E). If any additional emergency preparedness requirements are necessary, those requirements should be under the auspices of the OPTN and UNOS or coordinated by these organizations.

Response: We agree with the commenters that transplant centers have a long history of working well with each other. However, we also believe that transplant centers need to be proactive and make at least certain basic preparations for emergency situations. The OPTN does have emergency preparedness requirements. However, those requirements are not comprehensive, and we do not believe they are sufficient. For example, those policies cover the transportation of organs and communication interruptions between the OPTN contractor and transplant centers and OPOs. They do not cover local emergencies or even common emergency situations, such as weather-related events in which a transplant center may have a disruption in power or in getting its staff into the hospital. In addition, including emergency preparedness requirements in the transplant CoPs provides us with oversight and enforcement authority and imposes the requirements on transplant programs that received their designation by virtue of their approval for reimbursement for Medicare. The requirements finalized in this rule also should not conflict with the OPTN policies on emergency preparedness.

Comment: Some commenters stated that complying with the proposed requirements would be overly burdensome. Commenters indicated our burden estimates were extremely conservative and that the proposed agreements in § 483.78 could require more than 100 hours, especially for hospitals with multiple transplant programs, and perhaps as many as 200 contracts. In addition, some commenters also indicated that the proposed requirements would result in increased financial burden to patients and their families.

Response: We agree with the commenters. In analyzing the comments we received for the transplant center requirements, we now believe that some of these requirements, especially the proposed requirement for the transplant center to have an agreement with another transplant center, would likely require more resources than we originally estimated. There is also a possibility that there could be some increase in costs to patients and their families. Therefore, we are not finalizing these requirements as proposed for transplant centers to have agreements with other transplant centers or for the transplant center to ensure that the agreement between the hospital in which it is located and the OPO addresses the hospital and the OPO's duties and responsibilities during an emergency in the agreement required by § 486.100, as required in proposed § 482.78. Instead, we are finalizing requirements for transplant centers, the hospitals in which they are located, and the relevant OPOs in developing and maintaining protocols that address the duties and responsibilities of each party during an emergency. We believe the burden on transplant centers, patients, and their families will be less than estimated burden in the proposed rule. See section III.I. of this final rule (Collection of Information Requirements, ICRs Regarding Condition of Participation: Emergency Preparedness for Transplant Centers (§ 482.78)) for our revised burden estimate.

Comment: Many commenters believed that agreements for emergency preparedness between transplant centers would be of little value. Since the affected area during any particular emergency is unknown ahead of time, the transplant center may have an agreement with another transplant center that is also affected by the same emergency. They also noted that, since the circumstances of each natural and man-made disaster would be different, any plans made ahead of time may be unworkable during an actual emergency. They noted that, in each emergency, the affected geographic area has to be taken into consideration, in addition to the services and patients affected. In addition to being of little value, they noted that emergency plans may provide a false sense of security. Also, in some areas of the country, the great geographical distances between transplant centers would make agreements with another center both overly burdensome and impractical.

Response: We believe that emergency preparedness is essential for healthcare entities. Also, emergency preparedness plans should be flexible enough to allow for emergencies that affect both the local area, as well emergencies that may affect a larger area, such as regional and national emergencies. However, we do agree with the commenters that the great geographical distances between some of the transplant centers could result in making agreements between the centers burdensome and impractical. Therefore, we are not finalizing the requirement for agreements with between transplant centers as proposed. Instead, based on our analysis of the comments, we have decided to require that transplant centers be actively involved in their hospital's emergency planning and programming. We believe this requirement will ensure that the needs of each transplant center are addressed in the hospital's program. Also, transplant centers must be involved in the development of mutually-agreed upon protocols that addresses the duties and responsibilities of the hospital, transplant program, and OPO during emergencies. These changes are discussed in more detail later in this final rule.

Comment: Some commenters expressed concerns about how transferring transplant recipients and those on the waiting lists to another transplant center would affect both these patients and those at the receiving transplant center. Since each transplant program develops its own patient selection criteria and, if the transplant center performs living donor transplants, living donor selection criteria, this could result in some patients not being acceptable to the transplant center that agrees to care for patients from another transplant center that is experiencing an emergency. A commenter noted that OPTN Policy 3.4B prohibits transplant hospitals from registering a candidate on a waiting list for an organ if that transplant center does not have current OPTN approval for that type of organ (accessed at *http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf#nameddest=Policy_01* on February 24, 2015). In addition, depending upon the length of time of the emergency, there could be issues regarding how the waiting list patients would be integrated with the receiving transplant center's own waiting list patients. There was some concern that, depending on how the transfer was conducted, some of the transferring waiting list patients could receive preferential treatment over the receiving transplant center's waiting list patients. Also, there were some concerns about how patient records or other relevant information would be transferred. In addition, there was a concern about whether CMS and the OPTN would grant any exceptions or modifications to the required statistics and outcome measures during an emergency, especially if the transferring patients do not meet the receiving facility's selection criteria.

Response: We agree that there could be issues when patients are transferred from one transplant center to another. However, our requirements do not oblige a transplant center that agrees to care for another transplant center's patients during an emergency to put those patients on its waiting lists. We anticipate that most emergencies would be of short duration and that the transplant center that is affected by an emergency will resume its normal operations within a short period of time. However, if a transplant center does arrange for its patients to be transferred to another transplant center during an emergency, both transplant centers would need to determine what care would be provided to the transferring patients, including whether and under what circumstances the patients from the transferring transplant center would be added to the receiving center's waiting lists.

Concerning exceptions or modifications to the required statistics and outcome measures for operations during an emergency, we believe that is beyond the scope of this final rule. We would note that the current survey, certification, and enforcement procedures already provide for transplant centers to request consideration for mitigating factors in both the initial and re-approval processes for their center as set forth in § 488.61(f). In addition, there are specific requirements for requests related to natural disasters and public health emergencies (§ 488.61(f)(2)(vii)).

Comment: Some commenters expressed concern that our proposed requirements would interfere with or contradict OPTN policies. A commenter specifically noted that, in the preamble to the proposed rule, we stated that "[i]deally, the Medicare-approved transplant center that agrees to provide care for a center's patients during an emergency would perform the same type of organ transplant as the center seeking the agreement. However, we recognize that this may not always be feasible. Under some circumstances, a transplant center may wish to establish an agreement for the provision of post-transplant care and follow-up for its patients with a center that is Medicare-approved for a different organ type" (78 FR 79108). The commenter noted that OPTN Policy 3.4.B states that "[m]embers are only permitted to register a candidate on the waiting list for an organ at a transplant program if the transplant program has current OPTN transplant program approval for that organ type."

Response: We disagree with the commenters. We do not expect any transplant center to violate any of the OPTN's policies. We are not finalizing the proposed requirement for transplant centers to have agreements with another transplant center because we now believe that requirement may be burdensome and impractical for some transplant centers as we have discussed earlier. However, if a transplant center choses to have an agreement with another transplant center to care for its patients during an emergency, there is no requirement for the receiving center to place those patient on its waiting lists. The receiving transplant center would likely only provide care for the duration of the emergency and then those patients would return to their original transplant center. However, what care was to be provided should be decided by the transplant centers prior to any emergency. Also, as stated earlier, the OPTN's policies are not comprehensive. For example, they do not cover local emergencies or the other specific requirements in this final rule, that is, requirements for a risk assessment, specific policies and procedures, an emergency plan, a communication plan, and training and testing. In addition, as described earlier, including emergency preparedness requirements in the transplant center CoPs provides us with oversight and enforcement authority we do not have for the OPTN policies.

Comment: A few commenters stated that the proposed transplant center requirements were unnecessary. The transplant center should be embedded in the hospital's overall emergency plan so that transplant patients would be considered along with all of the other patients in the hospital. Another commenter suggested that this agreement not be between different transplant centers but the hospitals in which they are located, or even part of a larger or regional emergency plan.

Response: We agree with the commenters that the transplant center's emergency preparedness plans should be included in the hospital's emergency plans. All of the Medicare-approved transplant centers are located within hospitals and, as part of the hospital, should be included in the hospital's emergency preparedness plans. In addition, if transplant centers were required to separately comply with all of the requirements in § 482.15, it would be tremendously burdensome to the transplant centers. For example, we believe that the transplant center needs to be involved in the hospital's risk assessment because there may be risks to the transplant center that others in the hospital may not be aware of or appreciate. However, most of the risk assessment would be the same since the transplant center is located in the hospital; a separate risk assessment would unnecessary and overly burdensome. Therefore, we have modified § 482.68(b) so that transplant centers are exempt from the emergency preparedness requirements in § 482.15 and added a requirement in § 482.15(g) that requires transplant hospitals to have a representative from each transplant center actively involved in the development and maintenance of the hospital's emergency preparedness program. In addition, transplant centers would still be required to have their own emergency preparedness policies and procedures, as well as participate in mutually-agreed upon protocols that address the transplant center, hospital, and OPO's duties and responsibilities during an emergency.

Comment: Some commenters recommended that, instead of requiring agreements between transplant centers and OPOs as we had proposed, we should require hospitals, transplant centers, and OPOs to develop mutually agreed-upon protocols for addressing emergency situations. These commenters pointed out that since we proposed that emergency plans be reviewed and updated annually and that changes be incorporated based upon new information, protocols would be more conducive to timely and effective improvement. Other commenters noted that certain factors that would need to be considered in an emergency, particularly the different facility-specific levels of service, geographically based hazards, and donor potentials, were inappropriate for formal agreements but were well suited for protocols.

Response: We agree with the commenters. We believe that mutually agreed-upon protocols between the transplant centers, the hospitals in which the transplant centers operate, and the OPOs are the best approach to address emergency preparedness for these facilities. Therefore, we are not finalizing the requirement at proposed § 482.78 that a transplant center or the hospital in which it operates have an agreement with another transplant center, or the requirement that the agreement required at § 486.100 include the duties and responsibilities of the OPO and hospital during an emergency. Instead, we have revised the requirements for transplant centers, the hospitals in which they operate, and OPOs to specify that these facilities must have mutually agreed-upon protocols that state the duties and responsibilities of each during an emergency. We believe this approach will not only achieve our goal of having these facilities prepared for emergencies but will also impose only minimal burden. Section 486.344(d) currently requires that OPOs have protocols with transplant centers and § 482.100 requires that transplant centers ensure that the hospitals in which they operate have written agreements for the receipt of organs with an OPO designated by the Secretary that identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation according to § 482.100. In addition, since most, if not all, of these facilities must have previously encountered emergencies, we believe that establishing these protocols should require a much smaller burden than developing an agreement.

After consideration of the comments we received on those changes in the proposed rule, as discussed earlier and in the hospital section (section II.C. of this final rule), we are finalizing the proposed emergency preparedness requirements for transplant centers with the following modifications:

- Adding a requirement at § 482.15(g) that a transplant center be actively involved in the hospital's emergency preparedness planning and program, and the phrase "as defined by § 482.70".
- Modifying § 482.68(b) to exempt transplant centers from the requirements in § 482.15.
- Removing the requirement in § 482.78 for transplant centers to have agreements with another transplant center.
- Modifying the requirement in § 482.78(b) to require that a transplant center be responsible for developing and maintaining mutually agreed upon protocols that address the duties and responsibilities of the transplant center, hospital, and OPO during an emergency.
- Adding "as defined by § 482.70" that sets forth the definition of a "transplant hospital" to clarify which hospitals are responsible for complying with § 482.15(g).

J. Emergency Preparedness Requirements for Long Term Care (LTC) Facilities (§ 483.73)

Section 1819(a) of the Act defines a skilled nursing facility (SNF) for Medicare purposes as an institution or a distinct part of an institution that is primarily engaged in providing skilled nursing care and related services to patients that require medical or nursing care or rehabilitation services due to an injury, disability, or illness. Section 1919(a) of the Act defines a nursing facility (NF) for Medicaid purposes as an institution or a distinct part of an institution that is primarily engaged in providing to patients: skilled nursing care and related services for patients who require medical or nursing care; rehabilitation services due to an injury, disability, or illness; or, on a regular basis, health-related care and services to individuals who due to their mental or physical condition require care and services (above the level of room and board) that are available only through an institution.

To participate in the Medicare and Medicaid programs, long-term care (LTC) facilities must meet certain requirements located at part 483, Subpart B, Requirements for Long Term Care Facilities. SNFs must be certified as meeting the requirements of section 1819(a) through (d) of the Act. NFs must be certified as meeting section 1919(a) through (d) of the Act. A LTC facility may be both Medicare and Medicaid approved.

LTC facilities provide a substantial amount of care to Medicare and Medicaid beneficiaries, as well as "dually eligible individuals" who qualify for both Medicare and Medicaid. As of June 2016, there were 15,699 LTC facilities and these facilities provided care for about 1.7 million patients.

The existing requirements for LTC facilities contain specific requirements for emergency preparedness, set out at § 483.75(m)(1) and (2). Section 483.75(m)(1) states that a facility must have detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing residents. We proposed that this language be incorporated into proposed § 483.73(a)(1). Existing § 483.75(m)(2) states that a facility must train all employees in emergency procedures when they begin to work in the facility, periodically review the procedures with existing staff, and carry out unannounced staff drills using those procedures. These requirements would be incorporated into proposed § 483.73(d)(1) and (2). Section 483.75(m)(1) and (2) would be removed.

Our proposed emergency preparedness requirements for LTC facilities are identical to those we proposed for hospitals at § 482.15, with two exceptions. Specifically, at § 483.73(a)(1), we proposed that in an emergency situation, LTC facilities would have to account for missing residents.

Section 483.73(c) would requires these facilities to develop an emergency preparedness communication plan, which would include, among other things, a means of providing information about the general condition and location of residents under the facility's care. We proposed to add an additional requirement at § 483.73(c)(8) that read, "A method for sharing information from the emergency plan that the facility has determined is appropriate with residents and their families or representatives."

Also, we proposed at § 483.73(e)(1)(i) that LTC facilities must store emergency fuel and associated equipment and systems as required by the 2000 edition of the Life Safety Code (LSC) of the NFPA®. In addition to the emergency power system inspection and testing requirements found in NFPA® 99, NFPA® 101, and NFPA® 110, we proposed that LTC facilities test their emergency and stand-by-power systems for a minimum of 4 continuous hours every 12 months at 100 percent of the power load the LTC facility anticipates it would require during an emergency.

However, we also solicited comments on whether there should be a specific requirement for "residents' power needs" in the LTC requirements.

Comment: Some commenters recommended that LTC facilities be required to include patients, their families, and relevant stakeholders throughout the emergency preparedness planning and testing process. They recommended that the method of providing information from the emergency plan be clearly communicated with residents, representatives, and caregivers and that the LTC facilities follow a specific time frame to provide this communication. Some commenters recommended that PACE facilities and HHAs be required to include patients and their families in the emergency preparedness planning as well.

A few commenters recommended that LTC facilities include their state Long-Term Care Ombudsman Program in this planning process. Some commenters also recommended that LTC facilities provide the Program with a completed emergency plan.

Response: As we stated in the proposed rule, LTC facilities are unlike many of the inpatient care providers. Many of the residents have long term or extended stays in these facilities. Due to the long term nature of their stays, these facilities essentially become the residents' homes. We believe this fact changes the nature of the relationship with the residents and their families or representatives.

We continue to believe that each facility should have the flexibility to determine the information that is most appropriate to be shared with its residents and their families or representatives and the most efficient manner in which to share that information. Therefore, we are finalizing our proposal at § 483.73(c)(8) that LTC facilities develop and maintain a method for sharing information from the emergency plan that the facility has determined is appropriate with residents and their families or representatives. We note that we are not requiring that PACE and HHA providers share information from the emergency plan with families and their representatives. However, these providers can choose to share information with any appropriate party, so long as they comply with federal, state, and local laws.

We are not requiring LTC facilities to share information with stakeholders, or Long-Term Care Ombudsman Program representatives, because we believe such a requirement could be overly burdensome for the LTC facilities. We believe that facilities need the flexibility to develop their emergency plans and determine what portions of those plans and the parties with whom those plans should be shared. If a facility determines that it is appropriate and timely to share either the complete emergency plan, or certain portions of it, with stakeholders or representatives from the Long-Term Care Ombudsman Program, we encourage them to do so. Therefore, we are finalizing our proposal at § 483.73(c)(2)(iii) that LTC facilities maintain the contact information for the Office of the State Long-Term Care Ombudsman.

Comment: A majority of commenters expressed support for the proposal that requires LTC facilities to develop a communications plan. A few commenters also supported CMS' proposal to require LTC facilities to share information from the emergency plan that the facility has determined is appropriate with residents and their families or representatives. A commenter recommended that LTC facilities follow a specific timeframe to provide this communication.

Response: We appreciate the commenters' support. We note that we are not requiring specific timeframes for LTC facility communications in these emergency preparedness requirements. We are allowing facilities the flexibility to make the determination on when emergency preparedness plans and information should be communicated with the relevant entities during an emergency or disaster.

Comment: A commenter specifically recommended that CMS issue guidance to facilities regarding steps to disseminate information about the emergency plan to the general public. These steps would include posting the plan on the facility's Web site, if available, making a hard copy available for review at the facility's front desk; providing a notice to residents upon entering a facility that they or their representative can receive a free electronic copy at any time by providing their email address, and proving a copy of the plan in electronic format to local entities that are a resource for families during a disaster. A commenter recommended that CMS require LTC facilities to make the plans available to residents and their representatives upon request. According to the commenter, information that the facility shares should be written in clear and concise language and the facility's Web site could be a place for current, updated information.

Response: We agree with the commenter that transparency in communication is important. Therefore, we are requiring that LTC facilities have a method for sharing appropriate information with residents and their families or representatives. Consistent with our belief that these emergency preparedness requirements should afford facilities flexibility, we do not believe that it is appropriate to require that LTC facilities take specific steps or utilize specific strategies to share these documents with residents and their families or representatives.

Comment: A commenter stated that the communication plan requirement is broad and will lead to inconsistent approaches for facilities. Furthermore, the commenter noted that this will cause compliance and enforcement of the rule to be subjective.

Response: The proposed emergency preparedness regulations provide the minimum requirements that facilities must follow. This allows a variety of facilities, ranging from small rural providers to large facilities that are part of a franchise or chain, the flexibility to develop communication plans that are specific to the needs of their resident population and facility. Additionally, we have written these regulations with the intention to allow for flexibility in how facilities develop and maintain their emergency preparedness plans.

In addition to the CoPs/CfCs, interpretative guidelines (IGs) will be developed for each provider and supplier types. We also note that surveyors will be provided training on the emergency preparedness requirements, so that enforcement of the rule will be based on the regulations set forth here.

Comment: A commenter noted that the proposed requirements for a communication plan for LTC facilities do not mention a waiver that would allow for sharing of client information, which would create a potential violation of HIPAA. Furthermore, the commenter requested clarification in the final rule.

Response: As we stated previously in this final rule, HIPAA requirements are not suspended during a national or public health emergency. Thus, the communication plan is to be created consistent with the HIPAA Rules. See *http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/emergency/hipaa-privacy. http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/emergency/hipaa-privacy-emergency-situations.pdf*, for more information on how HIPAA applies in emergency situations.

Comment: A commenter stated that LTC facilities should consider multiple options for transportation in planning for an evacuation. Another commenter recommended that there should be coordination between vendors that provide transportation services for LTC facility residents with other facilities and community groups to avoid having too many providers relying on a few vendors.

Response: We agree with the commenters that it is preferable for facilities to have multiple options for the provision of services, including transportation, and that those services be coordinated so that they are used efficiently. We also encourage facilities to coordinate with other facilities in their geographic area to determine if their arrangements with any service provider are realistic. For example, if two LTC facilities in the same city are depending upon the same transportation vendor to evacuate their residents, both facilities should ensure that the vendor has sufficient vehicles and personnel to evacuate both facilities. Also, we believe that the requirements for testing that are set forth in § 483.73(d)(2), especially the full-scale exercise, should provide facilities with the opportunity to test their emergency plans and determine if they need to include multiple options for services and whether those services have been coordinated.

Comment: Due to the difficulty that the training requirement would place on smaller LTC facilities, a commenter suggested that we allow training by video demonstration, webinar, or by association-sponsored programs where regional training can be given to the staff of several facilities simultaneously. The commenter pointed out that group training would also bring about more in-depth discussion, questions, and comments.

Response: We agree that these training styles could be beneficial. Our proposed requirement for emergency preparedness training does not limit training types to within the facility only.

Comment: CMS solicited comments on whether LTC facilities should be required to provide the necessary electrical power to meet a resident's individualized power needs. Some organizations recommended that the regulation include specific requirements for a "resident's power needs." However, many commenters were opposed to this requirement. Opposing commenters stated that in an emergency, based on the emergency and available resources, things such as medically sustaining life support equipment would be needed rather than a powered wheelchair and the individual facility would be best at making that determination. Some commenters recommended that the final regulation state that power needs would be managed by the providers based on priority to address critical equipment and systems both for individual needs as well as the needs of the entire facility.

Response: We appreciate the feedback that we received from commenters on this issue. We agree that the needs of the most vulnerable residents should be considered first and expect that facilities would take the needs of their most vulnerable population into consideration as part of their daily operations. At § 483.73(a)(3) we require that the facility's emergency plan address their resident population to include persons at-risk, the type of services the facility has the ability to provide in an emergency, and continuity of their operations. We agree with commenters, and want facilities to have the flexibility to conduct their risk assessment, individually assess their population, and determine in their plans how they will meet the individual needs of their residents. We believe that the individual power needs of the residents are encompassed within the requirement that the facility assess its resident population. Therefore, we are not adding a specific requirement for LTC facilities to provide the necessary power for a resident's individualized power needs. However, we encourage facilities to establish policies and procedures in their emergency preparedness plan that would address providing auxiliary electrical power to power dependent residents during an emergency or evacuating such residents to alternate facilities. If a power outage occurs during an emergency or disaster, power dependent residents will require continued electrical power for ventilators, speech generator devices, dialysis machines, power mobility devices, certain types of durable medical equipment, and other types of equipment that are necessary for the residents' health and well-being. We therefore reiterate the importance of protecting the needs of this vulnerable population during an emergency.

Comment: A commenter objected to our proposal to require LTC facilities to have policies and procedures that addressed alternate sources of energy to maintain sewage and waste disposal. The commenter indicated that the provision and restoration of sewage and waste disposal systems may well be beyond the operational control of some providers.

Response: We agree with the commenter that the provision and restoration of sewage and waste disposal systems could be beyond the operational control of some providers. However, we are not requiring LTC facilities to have onsite treatment of sewage or to be responsible for public services. LTC facilities would only be required to make provisions for maintaining the necessary services.

Comment: A commenter noted that the proposed requirements do not address the issue of regional evacuation. This commenter believed that this was an essential part of an emergency plan and that the plan must address transportation and accommodations for people with physical, intellectual, or cognitive impairments. The commenter also recommended that the regional evacuation plan account for long-term sheltering and that there be specific standards for sheltering-in-place. Also, they believed that LTC facilities should be required to adopt the 2007 EP checklist that was issued by CMS.

Response: We agree with the commenter that the emergency plans for LTC facilities should address regional as well as local evacuations and long-term as well as short-term sheltering-in-place. However, we are finalizing the requirement for the emergency plan to be based upon a facility-based and community-based risk assessment, utilizing an all-hazards approach (§ 483.73(a)(1)). The "all-hazards" approach includes emergencies that could affect only the facility as well as the community in which it is located and beyond. It also includes emergencies that are both short-term and long-term. When facilities are developing their risk assessments, they should be considering all of those possibilities. We disagree about the recommendation that we propose more specific standards on sheltering-in-place. We believe that each facility needs the flexibility to develop its own plans for sheltering-in-place for both short and long-term use. We also disagree about requiring adoption of the 2007 CMS EP checklist, which can be found at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/SandC_EPChecklist_Persons_LTCFacilities_Ombudsmen.pdf.* That checklist is a resource that facilities may use. In addition, over time CMS may publish updates or other checklists or facilities may choose to use tools from other resources.

Comment: A commenter agreed with us that LTC facilities should have plans concerning missing residents. The current LTC requirements require LTC facilities have plan for emergencies, including missing residents (§ 483.75(m)). However, the commenter also believed that this requirement could be confusing and that we should clarify that facilities should have plans to account for missing residents in both emergency and non-emergency situations.

Response: We agree with the commenter that LTC facilities must have plans concerning missing residents that can be activated regardless of whether the facility must activate its emergency plan. A missing resident is an emergency and LTC facilities must have a plan to account for or locate the missing resident.

Comment: Some commenters wanted more clarification on the requirements for LTC facilities to have policies and procedures that address subsistence needs for staff and residents, particularly related to medical supplies and temperature to protect resident health and safety and for safe and sanitary storage of provisions. A commenter requested additional guidance and clarification on medical supplies. They questioned whether "supplies" would include individual residents' medications and, if it did, how that affected prescribing limits, payment systems, access, etc. Furthermore, a commenter wanted clarification on power requirements for temperatures. Another commenter recommended we specify a minimum for all needed supplies and provisions.

Response: We have not required minimums for these types of requirements because they would vary greatly between facilities. Each facility is required to conduct a facility-based and community-based assessment that addresses, among other things, its resident population. From that assessment, each facility should be able to identify what it needs for its resident population, including what medical/pharmaceutical supplies it needs to maintain and its temperature needs for both its resident population and its necessary provisions. As to minimum time periods, each facility would need to determine those based on its assessment and any other applicable requirements.

Comment: A commenter recommended that we require specific types of medical documentation in proposed § 483.73(b)(5). The commenter specifically recommended the inclusion of resident demographics, allergies, diagnosis, list of medications and contact information (commonly referred to as the "face sheet").

Response: We appreciate the commenter's suggestion. Proposed § 483.73(b)(5) required that the facility have policies and procedures that address "A system of medical documentation that preserves resident information, protects confidentiality of resident information, and ensures records are secure and readily available." While the types of documentation the commenter identified will probably be included in that documentation, we believe that facilities need the flexibility to determine what will be included in the medical documentation and how they will develop these systems. Thus, we are finalizing this provision as proposed.

After consideration of the comments we received on the proposals, and the general comments we received on the proposed rule, as discussed earlier in the hospital section (section II.C. of this final rule), we are finalizing the proposed emergency preparedness requirements for LTC facilities with the following modifications:

- Revising the introductory text of § 483.73 by adding the term "local" to clarify that LTC facilities must also comply with local emergency preparedness requirements.
- Revising § 483.73(a) to change the term "ensure" to "maintain."
- Revising § 483.73(b)(1)(i) to state that LTC facilities must have policies and procedures that address the need to sustain pharmaceuticals during an emergency.
- Revising § 483.73(b)(2) by clarifying that tracking during and after the emergency applies to on-duty staff and sheltered residents. We have also revised paragraph (b)(2) to provide that if on-duty staff and sheltered residents are relocated during the emergency, the facility must document the specific name and location of the receiving facility or other location.
- Revising § 483.73(b)(5) to replace the phrase "ensures records are secure and readily available" to "secures and maintains availability of records."
- Revising § 483.73(b)(7) to replace the term "ensure" with "maintain."
- Revising § 483.73(c) by adding the term "local" to clarify that the LTC facility must develop and maintain an emergency preparedness communication plan that also complies with local laws.
- Revising § 483.73(c)(5) to clarify that the LTC facility must develop a means, in the event of an evacuation, to release patient information, as permitted under 45 CFR 164.510(b)(1)(ii).
- Revising § 483.73(d) by adding that each LTC facility's training and testing program must be based on the LTC facility's emergency plan, risk assessment, policies and procedures, and communication plan.
- Revising § 483.73(d)(1)(iv) to replace the phrase "Ensure that staff can demonstrate knowledge" with "Demonstrate staff knowledge."
- Revising § 483.73(d)(2)(i) by replacing the term "community mock disaster drill" with "full-scale exercise."
- Revising § 483.73(d)(2)(ii) to allow a LTC facility to choose the type of exercise it will conduct to meet the second annual testing requirement.
- Revising § 483.73(e)(1) and (2) by removing the requirement for additional generator testing.
- Revising § 483.73(e)(2)(i) by removing the requirement for an additional 4 hours of generator testing and by clarifying that LTC facilities must meet the requirements of NFPA® 99, 2012 edition and NFPA® 110, 2010 edition.
- Revising § 483.73(e)(3) by removing the requirement that LTC facilities maintain fuel quantities onsite and clarify that LTC facilities must have a plan to maintain operations unless the LTC facility evacuates.
- Adding § 483.73(f) to allow a separately certified LTC facility within a healthcare system to elect to be a part of the healthcare system's emergency preparedness program.
- Adding a new § 483.73(g) to incorporate by reference the requirements of 2012 NFPA® 99, 2012 NFPA® 101, and 2010 NFPA® 110.

K. Emergency Preparedness Regulations for Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICF/IIDs) (§ 483.475)

Section 1905(d) of the Act created the ICF/IID benefit to fund "institutions" with four or more beds to serve people with [intellectual disability] or other related conditions. To qualify for Medicaid reimbursement, ICFs/IID must be certified and comply with CoPs at 42 CFR part 483, subpart I, §§ 483.400 through 483.480. As of June 2016, there were 6,237 ICFs/IID, serving approximately 129,000 clients, and all clients receiving ICF/IID services must qualify financially for Medicaid assistance under their applicable state plan. Clients with intellectual disabilities who receive care provided by ICF/IIDs may have additional emergency planning and preparedness requirements. For example, some care recipients are non-ambulatory, or may experience additional mobility or sensory disabilities or impairments, seizure disorders, behavioral challenges, or mental health challenges.

Because ICF/IIDs vary widely in size and the services they provide, we expect that the risk analyses, emergency plans, emergency policies and procedures, emergency communication plans, and emergency preparedness training will vary widely as well. However, we believe each of them has the capability to comply fully with the requirements so that the health and safety of its clients are protected in the event of an emergency situation or disaster.

Thus, we proposed to require that ICF/IIDs meet the same requirements we proposed for hospitals, with two exceptions. At § 483.475(a)(1), we proposed that ICF/IIDs utilize an all-hazards approach, including plans for locating missing clients. We believe that in the event of a natural or man-made disaster, ICF/IIDs would maintain responsibility for care of their own client population but would not receive patients from the community. Also, because we recognize that all ICF/IIDs clients have unique needs, we proposed to require ICF/IIDs to "address the unique needs of its client population . . ." at § 483.475(a)(3).

In addressing the unique needs of their client population, we believe that ICF/IIDs should consider their individual clients' power needs. For example, some clients could have motorized wheelchairs that they need for mobility, or require a continuous positive airway pressure or CPAP machine, due to sleep apnea. We believe that the proposed requirements at § 483.475(a) (a risk assessment utilizing an all-hazards approach and that the facility address the unique needs of its client population) encompass consideration of individual clients' power needs and should be included in ICF/IIDs risk assessments and emergency plans.

As we stated earlier, the purpose of this final rule is to establish requirements to ensure that Medicare and Medicaid providers and suppliers are prepared to protect the health and safety of patients in their care during more widespread local, state, and national emergencies. We do not believe the existing requirements for ICF/IIDs are sufficiently comprehensive to protect clients during an emergency that impacts the larger community. However, we have been careful not to remove emergency preparedness requirements that are more rigorous than the additional requirements we proposed.

For example, our current regulations for ICF/IIDs include requirements for emergency preparedness. Specifically, § 483.430(c)(2) and (3) contain specific requirements to ensure that direct care givers are available at all times to respond to illness, injury, fire, and other emergencies. However, we did not propose to relocate these existing facility staffing requirements at § 483.430(c)(2) and (3) because they address staffing issues based on the number of clients per building and client behaviors, such as aggression. Such requirements, while related to emergency preparedness tangentially, are not within the scope of the emergency preparedness requirements for ICF/IIDs.

Current § 483.470, Physical environment, includes a standard for emergency plan and procedures at § 483.470(h) and a standard for evacuation drills at § 483.470(i). The standard for emergency plan and procedures at current § 483.470(h)(1) requires facilities to develop and implement detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing clients. This requirement will be relocated to proposed § 483.475(a)(1). Existing § 483.470(h)(1) will be removed.

Currently § 483.470(h)(2) states, with regard to a facility's emergency plan, that the facility must communicate, periodically review the plan, make the plan available, and provide training to the staff. These requirements are covered in proposed § 483.475(d). Current § 483.470(h)(2) will be removed.

ICF/IIDs are unlike many of the inpatient care providers. Many of the clients can be expected to have long term or extended stays in these facilities. Due to the long term nature of their stays, these facilities essentially become the clients' residences or homes. Section 483.475(c) requires these facilities to develop an emergency preparedness communication plan, which includes, among other things, a means of providing information about the general condition and location of clients under the facility's care. We did not indicate what information from the emergency plan should be shared or the timing or manner in which it should be disseminated. We believe that each facility should have the flexibility to determine the information that is most appropriate to be shared with its clients and their families or representatives and the most efficient manner in which to share that information. Therefore, we proposed to add an additional requirement at § 483.475(c)(8) that reads, "A method for sharing information from the emergency plan that the facility has determined is appropriate with clients and their families or representatives."

The standard for disaster drills set forth at existing § 483.470(i)(1) specifies that facilities must hold evacuation drills at least quarterly for each shift of personnel under varied conditions to ensure that all personnel on all shifts are trained to perform assigned tasks; ensure that all personnel on all shifts are familiar with the use of the facility's fire protection features; and evaluate the effectiveness of their emergency and disaster plans and procedures. Currently § 483.470(i)(2) further specifies that facilities must evacuate clients during at least one drill each year on each shift; make special provisions for the evacuation of clients with physical disabilities; file a report and evaluation on each evacuation drill; and investigate all problems with evacuation drills, including accidents, and take corrective action. Furthermore, during fire drills, facilities may evacuate clients to a safe area in facilities certified under the Health Care Occupancies Chapter of the Life Safety Code. Finally, at existing § 483.470(i)(3), facilities must meet the requirements of § 483.470(i)(1) and (2) for any live-in and relief staff they utilize. Because these existing requirements are so extensive, we proposed cross referencing § 483.470(i) (redesignated as § 483.470(h)) at proposed § 483.475(d).

Comment: A commenter recommended that CMS include language that would exclude community-based residential services servicing three or fewer residents. The commenter noted that implementing the same emergency preparedness requirements as ICF/IID facilities for community based residential services would be cost prohibitive.

Response: A community-based residential facility with less than 4 beds would not meet the definition of an ICF/IID and would not be covered under this regulation. We encourage facilities that are concerned about the implementation of emergency preparedness requirements to refer to the various resources noted in the proposed and final rules, and participate in healthcare coalitions within their community for support in implementing these requirements.

Comment: A commenter agreed with CMS' proposal that ICF/IID providers' communication plans be shared with the families of their clients. The commenter noted that an annual correspondence to families, with intermediate updates as changes or additions are made, should not be burdensome to facilities.

Response: We appreciate the commenter's support. We have not set specific requirements for when or how often ICF/IID facilities should correspond with families and their representatives. However, facilities can choose to correspond with clients' families and their representatives as frequently as they deem appropriate.

Comment: Multiple commenters expressed their opposition to the requirement for ICF/IIDs to hold evacuation drills at least quarterly for each shift for personnel under varied conditions. Each commenter stated that quarterly evacuation drills are costly and will require the unnecessary movement of clients which could result in liability issues as well as disrupt operations.

Response: The requirement for quarterly evacuation drills is one of the requirements in the existing regulations for ICF/IIDs at § 483.470(i) (proposed to be redesignated to § 483.470(h)). We stated in the proposed rule that the purpose of the rule was to establish requirements to ensure that Medicare and Medicaid providers and suppliers are prepared to protect the health and safety of patients in their care during a widespread emergency. While we did not believe that the existing requirements for ICF/IIDs are sufficiently comprehensive enough to protect clients during an emergency that impacts the larger community, we were careful not to remove emergency preparedness requirements that are more rigorous than those additional requirements we proposed. Therefore, we proposed to retain this requirement. We believe that, unlike many of the inpatient care providers due to the long term nature of their clients stays, ICF/IIDs have a heightened responsibility to ensure the safety of their clients given that these facilities essentially become the clients' residences or homes.

Comment: A commenter expressed their support for the emphasis that the proposed rule placed on drills and testing for this vulnerable population and pointed out that many accrediting organizations require ICF/IIDs to test their emergency management plans each year.

Response: We thank the commenter for their support and agree that drills and testing are an important aspect of developing a comprehensive emergency preparedness program.

Comment: A commenter stated that the proposed requirement to place a generator in each home and to test it annually would be extremely costly.

Response: We would like to clarify that we did not propose a requirement for generators to be placed in each ICF/IID facility. We proposed additional testing requirements for hospitals, CAHs, and LTC facilities. However, due to the numbers of comments we received stating that the requirement for additional testing would be overly burdensome and unnecessary. We have removed this requirement in the final rule.

After consideration of the comments we received on these provisions of the proposed rule, and the general comments we received, as discussed in the hospital section (section II.C. of this final rule), we are finalizing the proposed emergency preparedness requirements for ICF/IIDs with the following modifications:

- Revising the introductory text of § 483.475, by adding the term "local" to clarify that ICF/IIDs must also comply with local emergency preparedness requirements.
- Revising § 483.475(a)(4) by deleting the term "ensuring" and replacing the term "ensure" with "maintain."
- Adding at § 483.475(b)(1)(i) that ICF/IIDs must have policies and procedures that address the need to sustain pharmaceuticals during an emergency.
- Revising § 483.47(b)(2) by clarifying that tracking during and after the emergency applies to on-duty staff and sheltered clients. We have also revised paragraph (b)(2) to provide that if on-duty staff and sheltered residents are relocated during the emergency, the facility must document the specific name and location of the receiving facility or other location.
- Revising § 483.475(b)(5) to change the phrase "ensures records are secure and readily available" to "secures and maintains availability of records;" also revising paragraph (b)(7) to change the term "ensure" to "maintain."
- Revising § 483.475(b)(1), (b)(1)(ii)(A), and (b)(2) to replace the term "residents" to "clients." Throughout the preamble discussion, the terms "patients and residents" have been deleted and replaced with the term "client."
- Revising § 483.475(c) by adding the term "local" to clarify that ICF/IIDs must develop and maintain an emergency preparedness communication plan that also complies with local laws.
- Revising § 483.475(c)(5) to clarify that ICF/IIDs must develop a means, in the event of an evacuation, to release patient information, as permitted under 45 CFR 164.510(b)(1)(ii).
- Revising § 483.475(d) by adding that each ICF/IID's training and testing program must be based on the ICF/IID's emergency plan, risk assessment, policies and procedures, and communication plan.
- Revising § 483.475(d)(1)(iv) to replace the phrase "Ensure that staff can demonstrate knowledge" to "Demonstrate staff knowledge."
- Revising § 483.475(d)(2)(i) by replacing the term "community mock disaster drill" with "full-scale exercise."
- Revising § 483.475(d)(2)(ii) to allow an ICF/IIDs to choose the type of exercise it will conduct to meet the second annual testing requirement.
- Adding § 483.475(e) to allow a separately certified ICF/IID within a healthcare system to elect to be a part of the healthcare system's emergency preparedness program.

L. Emergency Preparedness Regulations for Home Health Agencies (HHAs) (§ 484.22)

Under the authority of sections 1861(m), 1861(o), and 1891 of the Act, the Secretary has established in regulations the requirements that a home health agency (HHA) must meet to participate in the Medicare program. Home health services are covered for qualifying elderly and people with disabilities who are beneficiaries under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program. These services include skilled nursing care, physical, occupational, and speech therapy, medical social work and home health aide services which must be furnished by, or under arrangement with, an HHA that participates in the Medicare program and must be provided in the beneficiary's home. As of June 2016, there were 12,335 HHAs participating in the Medicare program. The majority of HHAs are for-profit, privately owned agencies. There are no existing emergency preparedness requirements in the HHA Medicare regulations at part 484, subparts B and C.

We proposed to add emergency preparedness requirements at § 484.22, under which HHAs would be required to comply with some of the requirements that we proposed for hospitals. We proposed additional requirements under the HHA policies and procedures that would apply only to HHAs to address the unique circumstances under which HHAs provide services.

Specifically, we proposed at § 484.22(b)(1) that an HHA have policies and procedures that include plans for its patients during a natural or man-made disaster. We proposed that the HHA include individual emergency preparedness plans for each patient as part of the comprehensive patient assessment at § 484.55.

At § 484.22(b)(2), we proposed to require that an HHA to have policies and procedures to inform federal, state and local emergency preparedness officials about HHA patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment. Such policies and procedures must be in accord with the HIPAA Privacy Rule, as appropriate.

We did not propose to require that HHAs meet all of the same requirements that we proposed for hospitals. Since HHAs provide healthcare services only in patients' homes, we did not propose requirements for policies and procedures to meet subsistence needs (§ 482.15(b)(1)); safe evacuation (§ 482.15(b)(3)); or a means to shelter in place (§ 482.15(b)(4)). We would not expect an HHA to be responsible for sheltering HHA patients in their homes or sheltering staff at an HHA's main or branch offices. We did not propose to require that HHAs comply with the proposed hospital requirement at § 482.15(b)(8) regarding the provision of care and treatment at alternate care sites identified by the local health department and emergency management officials. With respect to communication, we did not propose requirements for HHAs to have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510 as we propose for hospitals at § 482.15(c)(5). We have also modified the proposed requirement for hospitals at § 482.15(c)(7) by eliminating the reference to providing information regarding the facility's occupancy. The term occupancy usually refers to bed occupancy in an inpatient facility. Instead, at § 484.22(c)(6), we proposed to require HHAs to provide information about the HHA's needs and its ability to provide assistance to the local health department authority having jurisdiction or the Incident Command Center, or designee.

Comment: Several commenters stated that, despite our efforts, our proposed requirements for HHAs were not tailored for organizations that provide home-based services. Commenters indicated that we did not provide a complete description of our vision for the role that HHAs would play during and emergency and requested more clarity. A commenter requested that we work with the stakeholder community to develop a better understanding of how HHAs function, the needs of their patients, the communities in which they deliver services, and their resources.

Response: We appreciate the commenters' feedback. Many patients depend on the services of HHAs nationwide and the effective delivery of quality home health services is essential to the care of illnesses and prevention of hospitalizations. It is imperative that HHAs have processes in place to address the safety of patients and staff and the continued provision of services in the event of a disaster or emergency. We do not envision that HHAs will perform roles outside of their capabilities during an emergency. In addition, some HHAs that have agreements with hospitals already assist hospitals when at surge capacity. Home care professionals also have first-hand experience working in non-structured care environments. This experience has proven to be helpful in situations where patients are trapped in their homes or housed in shelters during a disaster or emergency. We also believe that because HHAs provide home care, they have first-hand knowledge of medically compromised individuals who have the potential to be trapped in their homes and unable to seek safe shelter during an emergency. This information is invaluable to state and local emergency preparedness officials. All of these activities and resources that HHAs have are necessary for effective community emergency preparedness planning.

We understand that one approach may not work for some and that community involvement will depend on the specific needs and resources of the community. However, we believe that establishing these emergency preparedness requirements for HHAs, and the other provider and suppliers, encourages collaboration and coordination that allows for a consistent, yet flexible regulatory framework across provider and supplier types. We would expect that HHAs will be proactive in their role of collaborating in community emergency preparedness planning efforts on both the national and local level. Through these efforts we believe that stakeholders will gain the opportunities to educate and define their role in state and local emergency planning.

Comment: Many commenters from an advocacy organization for HHAs agreed with the requirement that HHAs have policies and procedures that include individual emergency preparedness plans for each patient as part of the comprehensive patient assessment. However, several commenters requested clarification regarding our proposal. Commenters indicated that often times, during an emergency, a home care patient or their family may make different decisions and evacuate the patient, which largely negates any benefit from individualized plans. Commenters stated that HHAs should be required to instead provide planning materials to each patient upon assessment to assist them with developing a personal emergency plan. Some commenters indicated that patients should develop their own emergency plans based on their unique circumstances and requiring home health nurses to prepare emergency plans for their patients falls outside the scope of their practice. Most of the commenters supported the inclusion of a requirement for home health patients to have a personal emergency plan, but noted that CMS should keep in mind that the individual plans are only a starting place to locate and serve patients and may not be applicable to every type of emergency. A commenter suggested that we not link the identification of the patients' needs during an emergency to the patient assessment, but rather require that it occur within the first two weeks after the start of care to allow for staff to ensure the patient's acute care needs are met and remain first priority. In addition, some commenters recommended that each HHA be required to provide new patients and their families with a copy of the HHA's emergency policy and to inform them of the requirement that each new patient receive an individual emergency service plan. They also recommended providing a copy of the HHA's policies to the long-term care ombudsman programs that are involved in home healthcare.

Response: We appreciate the comments that we received on this issue. As a result of the comments, we agree that further clarification is needed. We also agree that all patients, their families and caregivers should be provided with information regarding the HHA's emergency plan and appropriate contact information in the event of an emergency. We did not intend for HHAs to develop extensive emergency preparedness plans with their patients. We proposed that HHAs include individual emergency preparedness plans for each patient as part of the comprehensive patient assessment required at § 484.55. Specifically, current regulations at § 484.55 require that each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment that accurately reflects the patient's current health status. In addition, regulations at § 484.55(a)(1) require that a registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient. As such, we believe that HHAs are already conducting and developing patient specific assessments and during these assessments, we expect that it will be minimally burdensome for HHAs to instruct their staff to assess the patient's needs in the event of an emergency.

We expect that HHAs already assist their patients with knowing what to do in the event of an emergency and the possibility that they may need to provide self-care if agency personnel are not available. For example, discussions to develop the individualized emergency preparedness plans could include potential disasters that the patient may face within the home such as fire hazards, flooding, and tornados; and how to contact local emergency officials. Discussions may also include education on steps that can be taken to increase the patient's safety. The individualized plan would be the written answers and solutions as a result of these discussions and could be as simple as a detailed emergency card developed with the patient. As commenters have indicated that often time patients choose to negate their plans and evacuate, we would expect that HHAs would use the individualized emergency plan to instruct patients on agency notification protocols for patients that relocate during an emergency and provide patients with information about the HHAs emergency procedures. HHAs could also use the individualized emergency plan to identify out of state contacts for each patient if available. HHA personnel should document that these discussions occurred. We are not requiring that HHAs provide their emergency plan and policies to any long-term care ombudsman programs, but we would encourage cooperation between various agencies.

Comment: Several commenters stated that HHAs and hospices have not been included in community emergency preparedness planning initiatives, nor have they received additional emergency planning funding. The commenters therefore requested additional time and flexibility to comply with the requirements for a communication plan. A few commenters requested clarification on what a communication plan for HHAs would entail.

Response: We understand the commenters' concerns about HHA providers' inclusion in community emergency preparedness planning initiatives. We believe that an emergency preparedness plan will better prepare HHA providers in case of an emergency or disaster and help to facilitate communication between facilities and community emergency preparedness agencies.

In response to the request for additional time, we have set the implementation date of these requirements for 1 year following the effective date of this final rule to allow facilities time to prepare. We also refer readers to the many resources that have been referenced in the proposed and final rules for guidance on developing an emergency preparedness communication plan for HHAs. HHAs are also encouraged to collaborate and participate in their local healthcare coalition that will be able to help inform and enable them to better understand how other providers are implementing the rules as well as provide access to local health department and emergency management officials that participate in local healthcare coalitions.

Comment: A few commenters expressed concern about the proposal to require that HHAs develop arrangements with other HHAs and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to HHA patients. Commenters stated that it was unclear how a home-based patient is ''received'' by a similar entity. The commenters noted that because most home health is provided in the home of the patient, care can be suspended for a period of time. Commenters also indicated that home health patients are not transferred to other HHAs. A commenter also stated that home health patients should not be transferred to hospitals during an emergency. A home health patient could receive care at other care settings, including those set up through emergency management and other state and federal government agencies. The commenters requested that CMS take these accommodations into consideration when deciding whether to finalize this proposal.

Response: We agree with the commenters. We understand that most HHAs would not necessarily transfer patients to other HHAs during an emergency and, based on this understanding of the nature of HHAs, we believe that HHAs should not be required to establish arrangements with other HHAs to transfer and receive patients during an emergency. Therefore, we are not finalizing the proposed requirement at § 484.22(b)(6) and (c)(1)(iv). During an emergency, if a patient requires care that is beyond the capabilities of the HHA, we would expect that care of the patient would be rearranged or suspended for a period of time. However, we note that as required at § 484.22(b)(2), HHAs will be responsible to have procedures to inform State and local emergency preparedness officials about HHA patients in need of evacuation from their residences at any time due to an emergency situation, based on the patient's medical and psychiatric condition and home environment.

Comment: A commenter indicated that it was unrealistic for HHAs to ensure cooperation and collaboration of various levels of government entities. The commenter noted that while it is critical that HHAs seek inclusion in discussions and understand the emergency planning efforts in their area, it has proven difficult for HHAs to secure inclusion. The commenter requested that we eliminate the requirement for HHAs to include a process for ensuring cooperation and collaboration with various levels of government.

Response: We recognize that some aspects of collaborating with various levels of government entities may be beyond the control of the HHA. In general, we used the word ''ensure'' or ''ensuring'' to convey that each provider and supplier will be held accountable for complying with the requirements in this rule. However, to avoid any ambiguity, we have removed the term ''ensure'' and ''ensuring'' from the regulation text of all providers and suppliers and have addressed the requirements in a more direct manner. Therefore, we are finalizing this proposal to require that HHAs include in their emergency plan a process for cooperation and collaboration with local, tribal, regional, state, and federal emergency preparedness officials. As proposed, we also indicate that HHAs must include documentation of their efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

Comment: A few commenters requested further clarification in regards to our use of the term ''volunteers'' as it relates to HHAs. Commenters noted that HHAs are not required to use volunteers and that the role of volunteers is not addressed at all in § 484.113.

Response: We provided information on the use of volunteers in the proposed rule (78 FR 79097), specifically with reference to the Medical Reserve Corps and the ESAR–VHP programs. Private citizens or medical professionals not employed by a facility often offer their voluntary services to providers during an emergency or disaster event. Therefore, we believe that HHAs should have policies and procedures in place to address the use of volunteers in an emergency, among other emergency staffing strategies. We believe such policies should address, among other things, the process and role for integration of state or federally-designated healthcare professionals, in order to address surge needs during an emergency. As with previous emergencies, facilities may choose to utilize assistance from the MRC or they may choose volunteers through the federal ESAR–VHP program. However, we want to emphasis that the need and use of volunteers or both is left up to the discretion of each individual facility, unless indicated as otherwise in their individual regulations.

Comment: A commenter stated that HHA and hospice providers should receive classification as essential healthcare personnel to gain access to restricted areas, in order to integrate into community-wide emergency communication systems.

Response: We have no authority to declare HHA and hospice providers as essential healthcare personnel in their local emergency management groups. We suggest that facilities who would like to gain access to restricted areas discuss how they may obtain access to community-wide emergency communication systems with their state and local government emergency preparedness agencies.

Comment: A commenter expressed concern about the level of technology required for HHAs and hospices to implement the emergency preparedness requirements. The commenter stated that this technology is expensive and not readily available. The commenter also noted that many HHA and hospice providers provide services in rural areas where cell phone coverage is limited. The commenter also stated that it is dangerous for the staff of HHAs and hospices located in urban areas to carry smart phone technology. The commenter finally noted that few HHA and hospice agencies provide staff with smart or satellite phones.

Response: As we discussed previously in this final rule, we are not endorsing a specific alternate communication system nor are we requiring the use of certain specific devices because of the associated burden and the potential obsolescence of such devices. However, we expect that facilities would consider using alternate means to communicate with staff and federal, state, tribal, regional and local emergency management agencies. Facilities can choose to utilize the technology suggested in this rule or they can use other types of backup communication. For example, if an HHA provider has nurses that work in a rural area without cell phone coverage, we would expect that the HHA agency would have some other means of communicating with the nurse, should an emergency or disaster occur. These means do not necessarily have to require sophisticated technology, although the devices discussed previously are proven useful communication technology. HHA providers are only required to provide, in their communication plan, plans for primary and alternate means for communicating with their staff and emergency management agencies. Facilities are given the discretion to choose what approach works for their specific circumstance.

Comment: In general, most commenters supported the proposed standards requiring a HHA to have training and testing programs, but suggested some revisions. A commenter stated that we did not provide a direct link between the testing requirements and the other requirements proposed for HHAs.

Response: We thank the commenters for their support of our proposed training and testing requirements. We believe that the emergency plan and policies and procedures cannot be executed without the proper training of staff members to ensure they have an understanding of the procedures and testing to demonstrate its feasibility and effectiveness.

Comment: We received a few comments on our proposal to require HHAs to provide annual training to their staff. A commenter stated that a requirement for annual training in emergency preparedness is an outdated approach to ensuring the organization is ready to put its plan into effect should the need arise. The commenter recommended that we revise the requirement by emphasizing the need for HHAs to involve staff in testing and other activities that will reinforce understanding of policies, procedures and their role in the implementation of the emergency plan. Another commenter stated that ongoing annual training is unnecessary and duplicative. The commenter suggested that we require only initial emergency preparedness training upon hire. Once this initial training is completed, copies of the plans and procedures would be kept on hand and readily accessible in the event of an emergency. The commenter stated that this approach would ensure just as timely and effective a response to an emergency as annual education while requiring less training time of staff taking away from patient care.

Response: We thank the commenters for their comments and appreciate their recommendations. The requirement for annual training is a standard requirement of many Medicare CoPs. We believe that the requirement is not outdated and is necessary to ensure that staff is regularly updated on their agency's emergency preparedness procedures. In our proposed training and testing standards, we stated that we would require a HHA to provide training in their emergency preparedness procedures to all new and existing staff. We also stated that a HHA must ensure that staff can demonstrate knowledge of their agency's emergency procedures. The emergency preparedness plan should be more than a set of written instructions that is referred to in an emergency. Rather, it should consist of policies and procedures that are incorporated into the facility's daily operations so that it is prepared to respond effectively during a disaster. Regular training and testing will ensure consistent staff behavior during an emergency, and also help to identify and correct gaps in the plan. In addition, we believe that requiring annual training is consistent with the proposed requirement to annually update a HHAs emergency plan and policies and procedures. We believe that it is best practice for facilities to ensure that their staff is regularly informed and educated in order to be the most prepared during an emergency situation.

Comment: A few commenters expressed their concern in regard to our proposal to require HHAs to participate in a community mock disaster drill. The commenters acknowledged the benefits and necessity of participating in drills and exercises to determine the effectiveness of an agency's plan, but stated that conducting drills and exercises is costly, time consuming, and especially difficult for HHAs in remote areas. Taking into consideration all of the documentation required for HHA patients, multiple commenters requested additional flexibility for HHAs, indicating that requiring both an annual tabletop exercise and a community drill is outside of the capacity of many agencies, would disrupt and compromise patient care, and requested additional flexibility for HHAs. A commenter suggested that HHAs be encouraged, rather than required, to participate in a community disaster drill. Another commenter stated that HHAs in particular would need to employ an additional person to be responsible for exercise planning and preparation and would also need to stop providing patient care during the exercises. The commenter indicated that there is a more cost effective and efficient way to ensure a HHA and its staff understand their emergency procedures without taking away from patient care and adding cost. The commenter suggested that, for HHAs, we should require "discussion-based" exercises leading up to a community mock drill required every 5 years.

Response: We appreciate the feedback from these commenters. As discussed, many other providers and suppliers have shared similar concerns. Therefore, we have revised § 484.22 to provide that HHAs may choose which type of training exercise they want to conduct in order to fulfill their second testing requirement. In addition, we would encourage agencies to continue looking to their local county and state governments and local healthcare coalitions for opportunities to collaborate on their training and testing efforts, such as a community full-scale exercise.

After consideration of the comments we received on these proposals, and the general comments we received on the proposed rule, as discussed in the hospital section (section II.C. of this final rule), we are finalizing the proposed emergency preparedness requirements for HHAs with the following modifications:

- Revising the introductory text of § 484.22 by adding the term "local" to clarify that HHAs must also comply with local emergency preparedness requirements.
- Revising § 484.22(a)(4) by deleting the term "ensuring" and replacing the term "ensure" with "maintain."
- Revising § 484.22(b)(3) to require that in the event that there is an interruption in services during or due to an emergency, HHAs must have policies in place for following up with patients to determine services that are still needed. In addition, they must inform State and local officials of any on-duty staff or patients that they are unable to contact.
- Revising § 484.22(b)(4) to change the phrase "ensures records are secure and readily available" to "secures and maintains availability of records."
- Removing § 484.22(b)(6) that required that HHAs develop arrangements with other HHAs and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to HHA patients.
- Revising § 484.22(c) by adding the term "local" to clarify that the HHA must develop and maintain an emergency preparedness communication plan that also complies with local laws.
- Revising § 484.22(c)(1) to remove the requirement that HHAs include the names and contact information for "Other HHAs" in the communication plan.
- Revising § 484.22(d) by adding that each HHA's training and testing program must be based on the HHA's emergency plan, risk assessment, policies and procedures, and communication plan.

- Revising § 484.22(d)(1)(ii) by replacing the phrase "Ensure that staff can demonstrate knowledge" to "Demonstrate staff knowledge."
- Revising § 484.22(d)(2)(i) by replacing the term "community mock disaster drill" with "full-scale exercise."
- Revising § 484.22(d)(2)(ii) to allow a HHA to choose the type of exercise it will conduct to meet the second annual testing requirement.
- Adding § 484.22(e) to allow a separately certified HHA within a healthcare system to elect to be a part of the healthcare system's emergency preparedness program.

M. Emergency Preparedness Regulations for Comprehensive Outpatient Rehabilitation Facilities (CORFs) (§ 485.68)

Section 1861(cc) of the Act defines the term "comprehensive outpatient rehabilitation facility" (CORF) and lists the requirements that a CORF must meet to be eligible for Medicare participation. By definition, a CORF is a non-residential facility that is established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, sick, and persons with disabilities, at a single fixed location, by or under the supervision of a physician. As of June 2016, there were 205 Medicare-certified CORFs in the U.S.

Section 1861(cc)(2)(J) of the Act also states that the CORF must meet other requirements that the Secretary finds necessary in the interest of the health and safety of a CORF's patients. Under this authority, the Secretary has established in regulations, at part 485, subpart B, requirements that a CORF must meet to participate in the Medicare program.

Currently, § 485.64 "Conditions of Participation: Disaster Procedures" includes emergency preparedness requirements CORFs must meet. The regulations state that the CORF must have written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters. The regulation requires that all personnel be knowledgeable with respect to these procedures, be trained in their application, and be assigned specific responsibilities.

Currently, § 485.64(a) requires a CORF to have a written disaster plan that is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts. The other elements under § 485.64(a) require that CORFs have: (1) Procedures for prompt transfer of casualties and records; (2) procedures for notifying community emergency personnel; (3) instructions regarding the location and use of alarm systems and signals and firefighting equipment; and (4) specification of evacuation routes and procedures for leaving the facility.

Currently, § 485.64(b) requires each CORF to: (1) Provide ongoing training and drills for all personnel associated with the CORF in all aspects of disaster preparedness; and (2) orient and assign specific responsibilities regarding the facility's disaster plan to all new personnel within 2 weeks of their first workday.

We proposed that CORFs comply with the same requirements that would be required for hospitals, with appropriate exceptions.

Specifically, at § 485.68(a)(5), we proposed that CORFs develop and maintain the emergency preparedness plan with assistance from fire, safety, and other appropriate experts. We did not propose to require CORFs to provide basic subsistence needs for staff and patients as we proposed for hospitals at § 482.15(b)(1). Because CORFs are outpatient facilities, we did not propose that CORFs have a system to track the location of staff and patients under the CORF's care both during and after the emergency as we propose to require for hospitals at § 482.15(b)(2). At § 485.68(b)(1), we proposed to require that CORFs have policies and procedures for evacuation from the CORF, including staff responsibilities and needs of the patients.

We did not propose that CORFS have arrangements with other CORFs or other providers and suppliers to receive patients in the event of limitations or cessation of operations. Finally, we did not propose to require CORFs to comply with the proposed hospital requirement at § 482.15(b)(8) regarding alternate care sites identified by emergency management officials.

With respect to communication, we would not require CORFs to comply with a proposed requirement similar to that for hospitals at § 482.15(c)(5) that would require a hospital to have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510, although we are clarifying in this final rule that CORFs must establish communications plans that are in compliance with federal laws, including the HIPAA rules. In addition, CORFs would not be required to comply with the proposed requirement at § 482.15(c)(6), which would state that a hospital must have a means of providing information about the general condition and location of patients as permitted under 45 CFR 164.510(b)(4).

We proposed including in the CORF emergency preparedness provisions a requirement for CORFs to have a method for sharing information and medical documentation for patients under the CORF's care with other healthcare facilities, as necessary, to ensure continuity of care (see proposed § 485.68(c)(4)). At § 485.68(c)(5), we proposed to require CORFs to have a communication plan that include a means of providing information about the CORF's needs and its ability to provide assistance to the local health department or authority having jurisdiction or the Incident Command Center, or designee. We did not propose to require CORFs to provide information regarding their occupancy, as we propose for hospitals, since the term occupancy usually refers to bed occupancy in an inpatient facility.

We proposed to remove § 485.64 and incorporate certain requirements into § 485.68. This existing requirement at § 485.64(b)(2) would be relocated to proposed § 485.68(d)(1).

Currently, § 485.64 requires a CORF to develop and maintain its disaster plan with assistance from fire, safety, and other appropriate experts. We incorporated this requirement at proposed § 485.68(a)(5). Currently, § 485.64(a)(3) requires that the training program include instruction in the location and use of alarm systems and signals and firefighting equipment. We incorporated these requirements at proposed § 485.68(d)(1).

We did not receive any comments that specifically addressed the proposed rule as it relates to CORFs. However, after consideration of the general comments we received on the proposed rule, as discussed in the hospital section (section II.C. of this final rule, we are finalizing the proposed emergency preparedness requirements for CORFs with the following modifications:

- Revising the introductory text of § 485.68, by adding the term "local" to clarify that CORFs must also comply with local emergency preparedness requirements.
- Revising § 485.68(a)(4) by deleting the term "ensuring" and replacing the term "ensure" with "maintain."
- Revising § 485.68(b)(3) to replace the phrase "ensures records are secure and readily available" to "secures and maintains availability of records."
- Revising § 485.68(c), by adding the term "local" to clarify that the CORFs must develop and maintain an emergency preparedness communication plan that also complies with local laws.

- Revising § 485.68(d) by adding that each CORF's training and testing program must be based on the CORF's emergency plan, risk assessment, policies and procedures, and communication plan.
- Revising § 485.68(d)(1)(iv) to replace the phrase "Ensure that staff can demonstrate knowledge" to "Demonstrate staff knowledge."
- Revising § 485.68(d)(2)(i) by replacing the term "community mock disaster drill" with "full-scale exercise."
- Revising § 485.68(d)(2)(ii) to allow a CORF to choose the type of exercise it will conduct to meet the second annual testing requirement.
- Adding § 485.68(e) to allow a separately certified CORF within a healthcare system to elect to be a part of the healthcare system's emergency preparedness program.

N. Emergency Preparedness Regulations for Critical Access Hospitals (CAHs) (§ 485.625)

Sections 1820 and 1861(mm) of the Act provide that critical access hospitals participating in Medicare and Medicaid meet certain specified requirements. We have implemented these provisions in 42 CFR part 485, subpart F, Conditions of Participation for Critical Access Hospitals (CAHs). As of June 2016, there are 1,337 CAHs that must meet the CAH CoPs and 121 CAHs with psychiatric or rehabilitation distinct part units (DPUs). DPUs within CAHs must meet the hospital CoPs in order to receive payment for services provided to Medicare or Medicaid patients in the DPU.

CAHs are small, rural, limited-service facilities with low patient volume. The intent of designating facilities as "critical access hospitals" is to ensure access to inpatient hospital services and outpatient services, including emergency services, that meet the needs of the community.

If no patients are present, CAHs are not required to have onsite clinical staff 24 hours a day. However, a doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates. In addition, there must be a registered nurse, licensed practical nurse, or clinical nurse specialist on duty whenever the CAH has one or more inpatients. In the event of an emergency, existing requirements state there must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, on call and immediately available by telephone or radio contact and available onsite within 30 minutes on a 24-hour basis or, under certain circumstances for CAHs that meet certain criteria, within 60 minutes. CAHs currently are required to coordinate with emergency response systems in the area to establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.

CAHs are required at existing § 485.623(c), "Standard: Emergency procedures," to assure the safety of patients in non-medical emergencies by training staff in handling emergencies, including prompt reporting of fires; extinguishing of fires; protection and, where necessary, evacuation of patients, personnel, and guests; and cooperation with firefighting and disaster authorities. CAHs must provide for emergency power and lighting in the emergency room and for battery lamps and flashlights in other areas; provide for fuel and water supply; and take other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located. Since CAHs are required to provide emergency services on a 24-hour a day basis, they must keep equipment, supplies, and medication used to treat emergency cases readily available.

We proposed to remove the current standard at § 485.623(c) and relocate these requirements into the appropriate sections of a new CoP entitled, "Condition of Participation: Emergency Preparedness" at § 485.625, which would include the same requirements that we propose for hospitals.

We proposed to relocate current § 485.623(c)(1) to proposed § 485.625(d)(1). We proposed to incorporate current § 485.623(c)(2) into § 485.625(b)(1). Current § 485.623(c)(3) would be included in proposed § 485.625(b)(1). Current § 485.623(c)(4) would be reflected by the use of the term "all-hazards" in proposed § 485.625(a)(1). Section 485.623(d) would be redesignated as § 485.623(c).

Also, as discussed in section II.A.4 of the of this final rule we proposed at § 485.625(e)(1)(i) that CAHs must store emergency fuel and associated equipment and systems as required by the 2000 edition of the Life Safety Code (LSC) of the NFPA®. In addition to the emergency power system inspection and testing requirements found in NFPA® 99 and NFPA® 110 and NFPA® 101, we proposed that CAHs test their emergency and stand-by-power systems for a minimum of 4 continuous hours every 12 months at 100 percent of the power load the CAH anticipates it will require during an emergency.

Comment: A few commenters stated that since CAHs play an important role in rural communities, an immediate community response in the event of an emergency is critical.

Response: We agree with the commenters and we require CAHs, and all providers, to comply with all applicable federal, state, and local emergency preparedness requirements. We also encourage CAHs to participate in state-wide collaborations where possible.

Comment: A couple of commenters questioned the ability of CAHs to participate in an integrated health system to develop an emergency plan. They stated that providers and suppliers were encouraged throughout the proposed rule to plan together and with their communities to achieve coordinated responses to emergencies.

Response: As discussed previously in this rule, we agree that CAHs should be able to participate in an in integrated health system to develop a universal plan that encompasses one community-based risk assessment, separate facility-based risk assessments, integrated policies and procedures that meet the requirements for each facility, and coordinated communication plans, training and testing. Currently, a CAH that is a member of a rural health network has an agreement with at least one hospital in the network for patient referrals and transfers. The proposed requirement for a CAH's emergency preparedness communication plan states that the CAH must include contact information for other CAHs. However, to be consistent with an integrated approach, we have also changed the proposed requirements at § 485.625(c)(1)(iv) to state that CAHs should develop a communication plan that would require them to have contact information for other CAHs and hospitals or both.

We also received a number of comments pertaining to the proposed requirements for CAHs, most commenters addressing both hospitals and CAHs in their responses. Thus, we responded to the comments under the hospital section (section II.C. of this final rule). After consideration of the comments we received on the proposed rule, as discussed in section II.C of this final rule, we are finalizing the proposed emergency preparedness requirements for CAHs with the following:

- Revising the introductory text of § 485.625 by adding the term "local" to clarify that CAHs must also comply with local emergency preparedness requirements.
- Revising § 485.625(a)(4) by deleting the term "ensuring" and replacing the term "ensure with "maintain."
- Adding at § 485.625(b)(1)(i) that CAHs must have policies and procedures that address the need to sustain pharmaceuticals during an emergency.
- Revising § 485.625(b)(2) to remove the requirement for CAHs to track on-duty staff and patients after an emergency and clarifying that in the event staff and patients are relocated, the CAH must document the specific name and location of the receiving facility or other location to which on-duty staff and patients were relocated to during an emergency.
- Revising § 485.625(b)(5) to change the phrase "ensures records are secure and readily available" to "secures and maintains availability of records;" also revising paragraph (b)(7) to change the term "ensure" to "maintain"
- Revising § 485.625(c) by adding the term "local" to clarify that the CAHs must develop and maintain an emergency preparedness communication plan that also complies with local laws.
- Revising § 485.625(c)(1)(iv) by adding the phrase "and hospitals" to clarify that a CAH's communication plan must include contact information for other CAHs and hospitals in the area.
- Revising § 485.625(c)(5) to clarify that CAHs must develop a means, in the event of an evacuation, to release patient information, as permitted under 45 CFR 164.510(b)(1)(ii).
- Revising § 485.625(d) by adding that each CAH's training and testing program must be based on the CAH's emergency plan, risk assessment, policies and procedures, and communication plan.
- Revising § 485.625(d)(1)(iv) to replace the phrase "ensure that staff can demonstrate knowledge" to "demonstrate staff knowledge."
- Revising § 485.625(d)(2)(i) by replacing the term "community mock disaster drill" with "full-scale exercise."
- Revising § 485.625(d)(2)(ii) to allow a CAH to choose the type of exercise it will conduct to meet the second annual testing requirement.
- Revising § 485.625(e)(1) and (2) by removing the requirement for additional generator testing.
- Revising § 485.625(e)(2)(i) by removing the requirement for an additional 4 hours of generator testing and clarify that these facilities must meet the requirements of NFPA® 99 2012 edition, NFPA® 101 2012 edition, and NFPA® 110, 2010 edition.
- Revising § 485.625(e)(3) by removing the requirement that CAHs maintain fuel onsite and clarify that CAHs must have a plan to maintain operations unless the CAH evacuates.
- Adding § 485.625(f) to allow a separately certified CAH within a healthcare system to elect to be a part of the healthcare system's emergency preparedness program.
- Adding § 485.625(g) to incorporate by reference the requirements of 2012 NFPA® 99, 2012 NFPA® 101, and 2010 NFPA® 110.

O. Emergency Preparedness Regulation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (§ 485.727)

Under the authority of section 1861(p) of the Act, the Secretary has established CoPs that clinics, rehabilitation agencies, and public health agencies must meet when they provide outpatient physical therapy (OPT) and speech-language pathology (SLP) services. The CoPs are set forth at part 485, subpart H.

Section 1861(p) of the Act describes "outpatient physical therapy services" to mean physical therapy services furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient. The patient must be under the care of a physician.

The term "outpatient physical therapy services" also includes physical therapy services furnished to an individual by a physical therapist (in the physical therapist's office or the patient's home) who meets licensing and other standards prescribed by the Secretary in regulations, other than under arrangement with and under the supervision of a provider of services, clinic, rehabilitation agency, or public health agency, if the furnishing of such services meets such conditions relating to health and safety as the Secretary may find necessary. The term also includes SLP services furnished by a provider of services, a clinic, rehabilitation agency, or by a public health agency, or by others under an arrangement.

As of June 2016, there are 2,135 clinics, rehabilitation agencies, and public health agencies that provide outpatient physical therapy and speech-language pathology services. In the remainder of this proposed rule and throughout the requirements, we use the term "Organizations" instead of "clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services" for consistency with current regulatory language.

We believe these Organizations comply with a provision similar to our proposed requirement for hospitals at § 482.15(c)(7), which states that a communication plan must include a means of providing information about the hospital's occupancy, needs, and its ability to provide assistance, to the local health department and emergency management authority having jurisdiction, or the Incident Command Center, or designee. At § 485.727(c)(5), we proposed to require that these Organizations have a communication plan that include a means of providing information about their needs and their ability to provide assistance to the authority having jurisdiction (local and state agencies) or the Incident Command Center, or designee. We did not propose to require these Organizations to provide information regarding their occupancy, as we proposed for hospitals, since the term "occupancy" usually refers to bed occupancy in an inpatient facility.

The current regulations at § 485.727, "Disaster preparedness," require these Organizations to have a disaster plan. The plan must be periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from a disaster. Additionally, current § 485.727(a) requires that the facility have a plan in operation with procedures to be followed in the event of fire, explosion, or other disaster. Those requirements are addressed throughout the proposed CoP, and we did not propose including the specific language in our proposed rule.

However, existing § 485.727(a) also requires that the plan be developed and maintained with the assistance of qualified fire, safety, and other appropriate experts. Because this existing requirement is specific to existing disaster preparedness requirements for these organizations, we relocated the language to proposed § 485.727(a)(6).

Existing requirements at § 485.727(a) also state that the disaster plan must include: (1) Transfer of casualties and records; (2) the location and use of alarm systems and signals; (3) methods of containing fire; (4) notification of appropriate persons, and (5) evacuation routes and procedures. Because transfer of casualties and records, notification of appropriate persons, and evacuation routes are addressed under policies and procedures in our proposed language, we do not propose to relocate these requirements. However, because the requirements for location and use of alarm systems and signals and methods of containing fire are specific for these organizations, we proposed to relocate these requirements to § 485.727(a)(4).

Currently, § 485.727(b) specifies requirements for staff training and drills. This requirement states that all employees must be trained, as part of their employment orientation, in all aspects of preparedness for any disaster. This disaster program must include orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out his or her assigned role in case of a disaster. Because these requirements are addressed in proposed § 485.727(d), we did not propose to relocate them but merely to address them in that paragraph. Current § 485.727, "Disaster preparedness," would be removed.

We did not receive any comments that specifically addressed the proposed rule as it relates to clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services. However, after consideration of the general comments we received on the proposed rule, as discussed in the hospital section (section II.C. of this final rule, we are finalizing the proposed emergency preparedness requirements for these Organizations with the following modifications:

- Revising the introductory text of § 485.727 by adding the term "local" to clarify that the Organizations must also comply with local emergency preparedness requirements.
- Revising § 485.727(a)(5) by deleting the term "ensuring" and replacing the term "ensure" with "maintain."
- Revising § 485.727(b)(3) to change the phrase "ensures records are secure and readily available" to "secures and maintains availability of records."
- Revising § 485.727(c), by adding the term "local" to clarify that the Organizations must develop and maintain an emergency preparedness communication plan that also complies with local laws.
- Revising § 485.727(d) by adding that the Organization's training and testing program must be based on the organization's emergency plan, risk assessment, policies and procedures, and communication plan.
- Revising § 485.727(d)(1)(iv) to replace the phrase "ensure that staff can demonstrate knowledge" to "demonstrate staff knowledge."
- Revising § 485.727(d)(2)(i) by replacing the term "community mock disaster drill" with "full-scale exercise."
- Revising § 485.727(d)(2)(ii) to allow an Organization to choose the type of exercise it will conduct to meet the second annual testing requirement.
- Adding § 485.727(e) to allow a separately certified Organizations within a healthcare system to elect to be a part of the healthcare system's emergency preparedness program.

P. Emergency Preparedness Regulations for Community Mental Health Centers (CMHCs) (§ 485.920)

A community mental health center (CMHC), as defined in section 1861(ff)(3)(B) of the Act, is an entity that meets applicable licensing or certification requirements in the state in which it is located and provides the set of services specified in section 1913(c)(1) of the Public Health Service Act. Section 4162 of Public Law 101–508 (OBRA 1990), which amended section 1861(ff)(3)(A) and 1832(a)(2)(J) of the Act, includes CMHCs as entities that are authorized to provide partial hospitalization services under Part B of the Medicare program, effective for services provided on or after October 1, 1991. Section 1866(e)(2) of the Act and 42 CFR 489.2(c)(2) recognize CMHCs as providers of services for purposes of provider agreement requirements but only with respect to providing partial hospitalization services. In 2015 there were 362 Medicare-certified CMHCs.

We proposed that CMHCs meet the same emergency preparedness requirements we proposed for hospitals, with a few exceptions. At § 485.920(c)(7), we proposed to require CMHCs to have a communication plan that include a means of providing information about the CMHCs' needs and their ability to provide assistance to the local health department or emergency management authority having jurisdiction or the Incident Command Center, or designee.

We did not receive any comments that specifically addressed the proposed rule as it relates to CMHCs. However, after consideration of the general comments we received on the proposed rule, as discussed in the hospital section (section II.C. of this final rule), we are finalizing the proposed emergency preparedness requirements for CMHCs with the following modifications:

- Revising the introductory text of § 485.920 by adding the term "local" to clarify that CMHCs must also comply with local emergency preparedness requirements.
- Revising § 485.920(a)(4) by deleting the term "ensuring" and replacing the term "ensure" with "maintain."
- Revising § 485.920(b)(1) by clarifying that tracking during and after the emergency applies to on-duty staff and sheltered clients. We have also revised paragraph (b)(1) to provide that if on-duty staff and sheltered clients are relocated during the emergency, the facility must document the specific name and location of the receiving facility or other location.
- Revising § 485.920(b)(4) and (6) to change the phrase "ensures records are secure and readily available" to "secures and maintains availability of records." Also, we made changes in paragraph (b)(6) to replace the term "ensure" to "maintain."
- Revising § 485.920(c) by adding the term "local" to clarify that CMHCs must develop and maintain an emergency preparedness communication plan that also complies with local laws.
- Revising § 485.920(c)(5) to clarify that CMHCs must develop a means, in the event of an evacuation, to release patient information, as permitted under 45 CFR 164.510(b)(1)(ii).
- Revising § 485.920(d) by adding that each CMHC's training and testing program must be based on the CMHC's emergency plan, risk assessment, policies and procedures, and communication plan.
- Revising § 485.920(d)(1) to replace the phrase "ensure that staff can demonstrate knowledge" to "demonstrate staff knowledge."
- Revising § 485.920(d)(2)(i) by replacing the term "community mock disaster drill" with "full-scale exercise."
- Revising § 485.920(d)(2)(ii) to allow a CMHC to choose the type of exercise it will conduct to meet the second annual testing requirement.
- Adding § 485.920(e) to allow a separately certified CMHC within a healthcare system to elect to be a part of the healthcare systems emergency preparedness program.

Q. Emergency Preparedness Regulations for Organ Procurement Organizations (OPOs) (§ 486.360)

Section 1138(b) of the Act and 42 CFR part 486, subpart G, establish that OPOs must be certified by the Secretary as meeting the requirements to be an OPO and designated by the Secretary for a specific donation service area (DSA). The current OPO CfCs do not contain any emergency preparedness requirements. As of June 2016, there were 58 Medicare-certified OPOs that are responsible for identifying potential organ donors in hospitals, assessing their suitability for donation, obtaining consent from next-of-kin, managing potential donors to maintain organ viability, coordinating recovery of organs, and arranging for transport of organs to transplant centers. Our proposed requirements for OPOs to develop and maintain an emergency preparedness plan, were similar to those proposed for hospitals, with some exceptions.

Since potential donors are located within hospitals, at proposed § 486.360(a)(3), instead of addressing the patient population as proposed for hospitals at § 482.15(a)(3), we proposed that the OPO address the type of hospitals with which the OPO has agreements; the type of services the OPO has the capacity to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

We proposed only 2 requirements for OPOs at § 486.360(b): (1) A system to track the location of staff during and after an emergency; and (2) a system of medical documentation that preserves potential and actual donor information, protects confidentiality of potential and actual donor information, and ensures records are secure and readily available.

In addition, at § 486.360(c), we proposed only three requirements for an OPO's communication plan. An OPO's communication plan would be required to include: (1) Names and contact information for staff; entities providing services under arrangement; volunteers; other OPOs; and transplant and donor hospitals in the OPO's DSA; (2) contact information for federal, state, tribal, regional, or local health department and emergency preparedness staff and other sources of assistance; and (3) primary and alternate means for communicating with the OPO's staff, federal, state, tribal, regional, or local emergency management agencies. Unlike the requirement we proposed for hospitals at § 482.15(d)(2)(i) and (iii), we proposed at § 486.360(d)(2)(i) that an OPO be required only to conduct a tabletop exercise.

Finally, at § 486.360(e), we proposed that each OPO have agreement(s) with one or more other OPOs to provide essential organ procurement services to all or a portion of the OPO's DSA in the event that the OPO cannot provide such services due to an emergency. We also proposed that the OPO include within its agreements with hospitals required under § 486.322(a) and in the protocols with transplant programs required under § 486.344(d), the duties and responsibilities of the hospital, transplant program, and the OPO in the event of an emergency.

Comment: We proposed the OPOs should track their staff during and after an emergency. All of the comments we received regarding this requirement were supportive. Commenters requested that we clarify whether an electronic system will satisfy this requirement. Commenters indicated that many OPOs currently have a means to communicate with all staff electronically and request that they respond with their location (within an identified time period) if necessary. Commenters questioned whether this process would be sufficient to meet this requirement.

Response: We appreciate the commenters' feedback and agree that the means of communication described by commenters is sufficient to meet this requirement. However, we want to emphasize that this is not the only way OPOs may choose to meet this requirement. In the proposed rule, we indicated that OPOs have the flexibility to determine how best to track staff whether an electronic database, hard copy documentation, or some other method.

Comment: A few commenters agreed with the proposal that would require that communication plans include names and contact information for staff, entities providing services under arrangement, volunteers, other OPOs, and transplant and donor hospitals in the OPO's DSA. However, the commenters requested that CMS narrow the requirements for OPOs to include only individuals or entities providing services under arrangement to those entities that would provide services in or during an emergency situation, such as emergency contacts for building services (plumbing, electrical, etc.), transportation providers, laboratory testing, etc.

Another commenter also agreed with the importance of providing a communication plan with staff information, but disagreed with the requirement that all entities providing services under arrangement with an OPO should be contacted during an emergency. The commenter recommended that only vendors providing critical services be contacted.

Response: We are requiring that OPOs provide in their communication plan the names and contact information for staff, entities providing services under arrangement, volunteers, other OPOs, and transplant and donor hospitals in the OPO's DSA. We are also requiring that OPOs include the contact information for federal, state, tribal, regional, and local emergency preparedness staff. Facilities can choose to include the contact information of other entities in their communication plan; however, we are not narrowing the scope of our requirements in this section to only include those entities with which an OPO has an arrangement. We continue to believe that it is important that OPOs have contact information for all of the previously specified entities because the OPO cannot know before an emergency what entities or services it would need. Also, we do not believe that it is burdensome for OPOs to maintain contact information for these entities because we believe that maintenance of contact information for these various entities is part of the normal course of business.

Comment: Several commenters requested clarification on whether existing databases of contact information would satisfy the communication plan requirements. The commenters listed examples such as a hosted volunteer tracking system or UNOS' DonorNET, with external backups.

Response: Each OPO should develop and maintain its own separate contact list in order to satisfy the communication plan requirements. OPOs must include contact information for staff, entities providing services under arrangement, volunteers, other OPOs, transplant and donor hospitals in the OPO's DSA and federal, state, tribal, regional, and local emergency preparedness staff, and other sources of assistance. DonorNET and other hosted volunteer tracking systems may contain useful contact information that OPO providers can use during an emergency, but these systems do not replace the need for comprehensive contact lists in the provider's emergency preparedness communication plan.

Comment: In regard to our proposed requirements for OPOs to have training and testing programs, all the commenters agreed with our proposals, but requested clarification of the phrase "consistent with their expected roles." The commenters questioned whether this meant that an OPO is not required to perform emergency preparedness training to staff, vendors, and volunteers who are not expected to play a role in the OPOs emergency response.

Response: This final rule requires that all persons (those employed, contracted, or volunteering) who provide some service within an OPO must be trained on the OPOs emergency preparedness procedures, given that an emergency can take place at any time. All providers and suppliers types have the flexibility to determine the level of training that is need for each staff person. As the requirement states for OPOs, this level of training should be determined consistent with the persons expected role during an emergency. It does not eliminate the need for all persons to be trained; however, an OPO has the discretion to determine to what extent.

Comment: Most of the commenters did not agree with the proposed requirement that each OPO have an agreement with one or more other OPOs. These commenters stated that the requirement was unnecessary and too burdensome. They indicated that our estimate of 13 burden hours was extremely conservative and that possibly as many as 200 contracts would need to be modified to comply with the requirements in proposed § 486.360(e).

Response: We agree with the commenters. The majority of the commenters indicated that complying with this requirement would require much more than the estimated 13 burden hours. In reviewing their comments and our estimate, we believe that the requirement for an agreement with one or more OPOs should be modified. Based upon our analysis and comments submitted in response to the proposed rule, we have inserted alternate ways in which an OPO could plan to continue its operations. See § 486.360(e). See section III.O. of this final rule Collection of Information Requirements, ICRs Regarding Condition for Coverage: Emergency Preparedness (§ 486.360), for our current burden estimate.

We disagree with the commenters that the requirement for OPOs to have an agreement with another OPO is unnecessary. We believe each OPO should be prepared to continue its operations or at least those activities it deems essential during an emergency as required by § 486.360(e). However, as discussed later in this final rule, based on the comments we received, we have decided to provide alternate ways in which OPOs could satisfy this requirement, which are discussed as follows:

Comment: A commenter noted the difficulty in developing an emergency plan based upon the all-hazards approach. One OPO works with more than 170 hospitals. Each hospital had its own specific levels of service and donor potential. These hospitals also had different geographically-based hazards. All of these factors would need to be addressed or taken into account when developing an emergency program.

Response: The amount of resources that each OPO must expend to comply with the requirements in this final rule will vary depending upon many factors. The number of hospitals the OPO works with, the services that each hospital offers, and the geographical hazards for each of these hospitals are all factors that could affect how complex the emergency plan and program would need to be. And, all of these various factors would need to be addressed in the OPO's emergency plan. We realize developing emergency plans and programs can be challenging; however, since OPOs are already working with these hospitals and there are a wide-range of emergency planning tools available, as well as assistance from the OPTN and other organizations, we believe that OPOs will be able to develop their emergency preparedness plans and programs within the burden estimates we have developed.

Comment: As discussed earlier with transplant centers, several commenters expressed concerned about how the proposed OPO requirements could interfere with or even contradict OPTN policies on emergencies; the commenter specifically referenced OPTN 1.4 that addresses regional and national emergencies. Among other things, this policy requires OPTN members to notify the OPTN concerning any alternative arrangements of care during an emergency and provide additional information as needed to allow for clinical information to be properly accessed and shared with all parties involved in a donation or transplant event.

Response: We disagree with the commenters. We do not expect any OPO to violate any of the OPTN's policies. However, as stated earlier, the OPTN's policies are not comprehensive. For example, they do not cover local emergencies or the other specific requirement in this final rule, that is, requirements for a risk assessment using an all-hazards approach, an emergency plan, specific policies and procedures, a communication plan, and training and testing. In addition, as described earlier, including emergency preparedness requirements in the OPO CfCs provides us with oversight and enforcement authority we do not have for the OPTN policies. In addition, we do not believe that complying with any of the requirements in this final rule will result in any conflict with the OPTN's requirements.

Comment: Some commenters questioned whether OPOs that already had more than one location or office needed to have an agreement with another OPO to provide essential organ procurement services to all or a portion of their DSA in the event of an emergency. A commenter questioned if we had considered this as an alternative to the proposed agreement.

Response: We did not propose having multiple locations as an alternative to the proposed requirement to have an agreement with another OPO. However, as the commenters suggested, we do believe that having more than one location could certainly satisfy our concern that OPOs have the capability to continue their organ procurement responsibilities in the event of an emergency. Therefore, in finalizing this requirement, we have added two alternatives to the requirement for an OPO to have an agreement with another OPO (§ 486.360(e)). For OPOs with multiple locations, the OPO could satisfy this requirement if it had an alternate location within its DSA from which it could continue its operation during an emergency. Another alternative is if the OPO had a plan to relocate to an alternate location that is part of its emergency plan as required in § 486.360(a). If the emergency were to affect an area larger than the OPO's DSA, we would expect that the OPTN would assist the OPO (OPTN Policy 4.1).

Comment: Some commenters suggested that instead of having formal agreements, OPOs, transplant centers, and hospitals should be required to develop mutually agreed-upon protocols that address each facility's responsibilities during an emergency.

Response: We agree with the commenters. After reviewing the comments we received on the proposed transplant center and OPO emergency preparedness requirements, we believe that the best way to ensure that transplant centers, the hospitals in which they operate, and the OPOs are prepared for emergencies is to require the development of mutually agreed-upon protocols that address the hospital, transplant center, and OPO's duties and responsibilities during an emergency. Therefore, we have removed the requirements in proposed § 482.78(a), which required an agreement with at least one Medicare-approved transplant center, and § 482.78(b), which required that the transplant center ensure that the written agreement required under § 482.100 addresses the duties and responsibilities of the hospital and OPO during an emergency. Instead, we have finalized a requirement at § 486.360(e) that OPOs develop mutually-agreed upon protocols that address the duties and responsibilities of the hospital, transplant center, and OPO during emergencies. We are also requiring that transplant centers and the hospitals in which they operate develop mutually-agreed upon protocols. Therefore, all 3 facilities will need to work together to develop and maintain protocols that address emergency preparedness.

Comment: A commenter recommended that CMS revise language in the manual to cover the costs of transportation of brain-dead donors for organ procurement. Furthermore, the commenter recommended that transplant centers be permitted to record organs from brain-dead donors sent to OPO recovery centers in the ratio of Medicare usable organs to total organs on their costs reports. The commenter noted that this would facilitate implementation of the proposed emergency preparedness requirements.

Response: We believe it is extremely unlikely that brain-dead donors would need to be transported during an emergency. Most OPOs are not recovering brain-dead donors every day and might or might not choose to move a potential donor depending upon the donor's condition. However, we would encourage transplant centers, the hospitals in which they are located, and OPOs to address this possibility in their emergency preparedness protocols as finalized in this rule. In addition, the commenter's request involves changes to the state operations manual and Medicare's policy on cost reports. These are payment policy issues and are outside of the scope of this regulation.

After consideration of the comments we received on these provisions, and the general comments we received on the proposed rule, as discussed in the hospital section (section II.C. of this final rule, we are finalizing the proposed emergency preparedness requirements for OPOs with the following modifications:

- Revising the introductory text of § 486.360 by adding the term "local" to clarify that OPOs must also comply with local emergency preparedness requirements.
- Revising § 486.360(a)(4) by deleting the term "ensuring" and replacing the term "ensure" with "maintain."
- Revising § 486.360(b)(1) by clarifying that tracking during and after the emergency applies to on-duty staff and any staff that are relocated during an emergency. Also, we revised paragraph (b)(1) to provide that if on-duty staff are relocated during the emergency, the facility must document the specific name and location of the receiving facility or other location.
- Revising § 486.360(b)(2) to change the phrase "ensures records are secure and readily available" to secures and maintains availability of records."
- Revising § 486.360(c) by adding the term "local" to clarify that the OPO must develop and maintain an emergency preparedness communication plan that also complies with local laws.
- Revising § 486.360(d) by adding that each OPO's training and testing program must be based on the OPO's emergency plan, risk assessment using an all hazards approach, policies and procedures, and communication plan.
- Revising § 486.360(d)(1)(iv) to replace the phrase "ensure that staff can demonstrate knowledge" to "demonstrate staff knowledge."
- Revising the requirement in § 486.360(e) to require the development and maintenance of emergency preparedness protocols that are mutually agreed upon by the transplant center, hospital, and OPO.
- Revising § 486.360(e) to state that OPOs can satisfy the agreement requirement by having at least one other location from which they could operate from within their DSA or a plan to set up an alternate location during an emergency as part of its emergency plan as required by § 486.360(a).
- Adding § 486.360(f) to allow a separately certified OPO within a healthcare system to elect to be a part of the healthcare system's emergency preparedness program.

R. Emergency Preparedness Regulations for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (§ 491.12)

As of June 2016, there were a combined total of 11,500 RHCs and FQHCs. Section 1861(aa) of the Act sets forth the rural health clinic (RHC) and federally qualified health center (FQHC) services covered by the Medicare and Medicaid program. RHCs must be located in an area that is both a rural area and a designated shortage area.

Conditions for Certification for RHCs and Conditions for Coverage for FQHCs are found at 42 CFR part 491, subpart A. Current emergency preparedness requirements are found at § 491.6(c).

We proposed that the RHCs' and FQHCs' emergency preparedness plans address the type of services the facility has the capacity to provide in an emergency.

Although RHCs and FQHCs currently do not have specific requirements for emergency preparedness, they have requirements for "Emergency Procedures" found at § 491.6, under "Physical plant and environment." At § 491.6(c)(1), the RHC or FQHC must train staff in handling non-medical emergencies. This requirement would be addressed at proposed § 491.12(d)(1). At § 491.6(c)(2), the RHC or FQHC must place exit signs in appropriate locations. This requirement would be incorporated into our proposed requirement at § 491.12(b)(1), which would require RHCs and FQHCs to have policies and procedures for safe evacuation from the facility which includes appropriate placement of exit signs. Finally, at § 491.6(c)(3), the RHC or FQHC must take other appropriate measures that are consistent with the particular conditions of the area in which the facility is located. This requirement would be addressed throughout the proposed CfC for RHCs and FQHCs, particularly proposed § 491.12(a)(1), which requires the RHCs and FQHCs to perform a risk assessment based on an "all-hazards" approach. Current § 491.6(c) would be removed.

We proposed emergency preparedness requirements based on the requirements that we proposed for hospitals, modified to address the specific characteristics of RHCs and FQHCs. We do not believe all of these requirements are appropriate for RHCs/FQHCs, which serve only outpatients. We did not propose to require RHC/FQHCs to provide basic subsistence needs for staff and patients. Also, unlike that proposed for hospitals at § 482.15(b)(2), we did not propose that RHCs/FQHCs have a system to track the location of staff and patients in the facility's care both during and after the emergency.

At § 482.15(b)(3), we proposed that hospitals have policies and procedures for safe evacuation from the hospital, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance. Therefore, at § 491.12(b)(1), we proposed to require that RHCs/FQHCs have policies and procedures for evacuation from the RHC/FQHC, including appropriate placement of exit signs, staff responsibilities, and needs of the patients.

Unlike the requirement that was proposed for hospitals at § 482.15(b)(7), we did not propose that RHCs/FQHCs have arrangements with other RHCs/FQHCs or other providers and suppliers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to RHC/FQHC patients. We did not propose to require RHC/FQHCs to comply with the proposed hospital requirement at § 482.15(b)(8) regarding alternate care sites.

In addition, we would not require RHCs/FQHCs to comply with the proposed requirement for hospitals found at § 482.15(c)(5), which would require that a hospital have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510. Modified from what has been proposed for hospitals at § 482.15(c)(7), at § 491.12(c)(5), we proposed to require RHCs/FCHCs to have a communication plan that would include a means of providing information about the RHCs/FQHCs needs and their ability to provide assistance to the local health department or emergency management authority having jurisdiction or the Incident Command Center, or designee. We did not propose to require RHCs/FQHCs to provide information regarding their occupancy, as we propose for hospitals, since the term occupancy usually refers to bed occupancy in an inpatient facility.

Comment: A commenter supported CMS' proposal to exempt FQHCs from releasing patient information as permitted under HIPAA 45 CFR part 164 in the case of an emergency or disaster.

Another commenter opposed CMS' proposed requirements for a communication plan for RHCs and FQHCs. The commenter stated their belief that RHCs and FQHCs should provide some level of patient clinical information during a disaster. The commenter noted the importance of sharing patient information with other hospitals that may be receiving evacuated patients during an emergency or a disaster. Furthermore, the commenter noted that these records should be available online through an EMR or through another procedure for providing patient information.

Response: We appreciate the commenter's support. We continue to believe that RHCs and FQHCs should not be required to comply with the proposed requirement for hospitals, which would require that a hospital have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510. RHCs and FQHCs are not inpatient facilities that would transfer patients to another facility during an evacuation. Because they operate on an outpatient basis, whereby during an emergency the facility would close and cancel appointments, we do not believe that it is necessary for RHCs and FQHCs to be mandated to provide patient information during an evacuation. However, we note that RHCs and FQHCs are not precluded from including policies and procedures in their communication plan to share patient information during an emergency with other facilities. RHCs and FQHCs can include these policies and procedures if they believe it is appropriate for their facility.

Comment: A commenter stated that small facilities such as an FQHC or RHC should be exempt from conducting a risk assessment. Another commenter stated that clinics should be required to have a plan to utilize volunteers in an emergency.

Response: We disagree with removing the risk assessment requirement for FQHCs and RHC. As we have stated earlier in this document, conducting a risk assessment is essential to developing an emergency preparedness plan. Clinics will have the flexibility to include volunteers in their emergency plan as indicated by their individual risk assessments. We would expect RHCs and FQHCs to develop strategies for addressing emergency events identified by their risk assessments.

After consideration of the comments we received on these provisions, and the general comments we received on the proposed rule, as discussed previously and in the hospital section (section II.C. of this final rule, we are finalizing the proposed emergency preparedness requirements for RHCs and FQHCs with the following modifications:

- Revising the introductory text of § 491.12 by adding the term "local" to clarify that RHCs and FQHCs must also coordinate with local emergency preparedness requirements.
- Revising § 491.12(a)(4) by deleting the term "ensuring" and replacing the term "ensure" with "maintain."
- Revising § 491.12(b)(3) to change the phrase "ensures records are secure and readily available" to "secures and maintains availability of records."
- Revising § 491.12(c) by adding the term "local" to clarify that RHCs and FQHCs must develop and maintain an emergency preparedness communication plan that also complies with local laws.
- Revising § 491.12(d) by adding that a RHC and FQHC's training and testing program must be based on the RHC and FQHC's emergency plan, risk assessment, policies and procedures, and communication plan.
- Revising § 491.12(d)(1)(iv) to replace the phrase "ensure that staff can demonstrate knowledge" to "demonstrate staff knowledge."
- Revising § 491.12(d)(2)(i) by replacing the term "community mock disaster drill" with "full-scale exercise."
- Revising § 491.12(d)(2)(ii) to allow a RHC and FQHC to choose the type of exercise it will conduct to meet the second annual testing requirement.
- Adding § 491.12(e) to allow separately certified RHCs and FQHCs within a healthcare system to elect to be a part of the healthcare system's emergency preparedness program.

S. Emergency Preparedness Regulation for End-Stage Renal Disease (ESRD) Facilities (§ 494.62)

Sections 1881(b), 1881(c), and 1881(f)(7) of the Act establish requirements for end-stage renal disease (ESRD) facilities. ESRD is a kidney impairment that is irreversible and permanent and requires either a regular course of dialysis or kidney transplantation to maintain life. Dialysis is the process of cleaning the blood and removing excess fluid artificially with special equipment when the kidneys have failed. As of June 2016, there were 6,648 Medicare-participating ESRD facilities in the U.S.

We addressed emergency preparedness requirements for ESRD facilities in the April 15, 2008 final rule (73 FR 20370) titled, "Conditions for Coverage for End-Stage Renal Disease Facilities; Final Rule." Emergency preparedness requirements are located at § 494.60(d), Condition: Physical environment, Standard: Emergency preparedness. We proposed to relocate these existing requirements to proposed § 494.62, Emergency preparedness.

Current regulations include the requirement that dialysis facilities be organized into ESRD Network areas. Our regulations describe these networks at § 405.2110 as CMS-designated ESRD Networks in which the approved ESRD facilities collectively provide the necessary care for ESRD patients. The ESRD Networks have an important role in an ESRD facility's response to emergencies, as they often arrange for alternate dialysis locations for patients and provide information and resources during emergency situations. As noted earlier, we do not propose incorporating the ESRD Network requirements into this proposed rule. We did not propose to require ESRD facilities to provide basic subsistence needs for staff and patients, whether they evacuate or shelter in place, including food, water, and medical supplies; alternate sources of energy to maintain temperatures to protect patient health and safety and for the safe and sanitary storage of provisions; emergency lighting; and fire detection, extinguishing, and alarm systems; and sewage and waste disposal as we proposed for hospitals at § 482.15(b)(1).

At § 494.62(b), we proposed to require facilities to address in their policies and procedures, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters in the facility's geographic area.

At § 482.15(b)(3), we proposed that hospitals have policies and procedures for the safe evacuation from the hospital, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance. We do not believe all of these requirements are appropriate for ESRD facilities, which serve only outpatients. Therefore, at § 494.62(b)(2), we proposed to require that ESRD facilities have policies and procedures for evacuation from the facility, including staff responsibilities and needs of the patients.

At § 494.62(b)(6), we proposed to require ESRD facilities to develop arrangements with other dialysis facilities or other providers and suppliers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to dialysis facility patients. At § 494.62(c)(7), dialysis facilities would be required to comply with the proposed requirement for hospitals at § 482.15(c)(7), with one exception. At § 494.62(c)(7), we proposed to require dialysis facilities to have a communication plan that include a means of providing information about their needs and their ability to provide assistance to the authority having jurisdiction or the Incident Command Center, or designee. We did not propose to require dialysis facilities to provide information regarding their occupancy, as we proposed for hospitals, since the term occupancy usually refers to bed occupancy in an inpatient facility.

At § 494.62(d)(1)(i), we proposed to require ESRD facilities to ensure that staff can demonstrate knowledge of various emergency procedures, including: informing patients of what to do; where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated; and whom to contact if an emergency occurs while the patient is not in the dialysis facility.

We proposed to relocate existing requirements for patient training from § 494.60(d)(2) to proposed § 494.62(d)(3), patient orientation. In addition, the facility would have to ensure that, at a minimum, patient care staff maintained current CPR certification and ensure that nursing staff were properly trained in the use of emergency equipment and emergency drugs.

We proposed to redesignate current § 494.60(d). Current requirements for emergency plans at § 494.60 were captured within proposed § 494.62(a). Current language that defines an emergency for dialysis facilities found at § 494.60(d) would be incorporated into proposed § 494.62(b). We proposed to relocate existing requirements for emergency equipment and emergency drugs found at existing § 494.60(d)(3) to § 494.62(b)(9). We proposed to relocate the existing requirement at § 494.60(d)(4)(i) that requires the facility to have a plan to obtain emergency medical system assistance when needed to proposed § 494.62(b)(8). We proposed to relocate the current requirements at § 494.60(d)(4)(iii) for contacting the local health department and emergency preparedness agency at least annually to ensure that the agency is aware of dialysis facility's needs in the event of an emergency to proposed § 494.62(a)(4). We also proposed to redesignate the current § 494.60(e) as § 494.60(d).

Comment: Some commenters agreed with the proposal to require ESRD providers to develop and maintain an emergency preparedness communication plan. Several commenters disagreed with the implementation of the emergency preparedness communication plan requirements for dialysis facilities. A commenter noted that the current CfCs require dialysis facilities to have at least annual contact with the local disaster management agency.

A commenter agreed with the proposal that exempts ESRD facilities from having to provide information regarding occupancy since, according to the commenter, the facilities do not serve outpatient and do not routinely accommodate overnight stays.

Response: We appreciate the commenters' support. We continue to believe that ESRD facilities should develop and maintain a communication plan so that the facility can be prepared to communicate with the local health department, emergency management and other emergency preparedness officials during an emergency or a disaster. We are not requiring dialysis facilities to provide information regarding their occupancy, as we are requiring for hospitals, since the term occupancy refers to bed occupancy in an inpatient facility.

Comment: A commenter stated that the language used in this section was vague and erroneously technical. This commenter specifically noted that the term "community mock disaster drill" in § 494.62(d)(2)(i) was not consistent with the terminology used in the document, Homeland Security Exercise and Evaluation Program Terminology, Methodology, and Compliance Guidelines (HSEEP). The term "Incident Command Center" in § 494.62(c)(7) is not an Incident Command System (ICS) or National Incident Management System (NIMS) term.

Response: We understand that the commenter is concerned with this rule's inconsistencies with terminology used in the disaster and emergency response planning community. Providers and suppliers use various terms to refer to the same function and we have used the term "Incident Command Center" in this rule to mean "Operations Center" or "Incident Command Post." After this final rule is published, interpretive guidance will be published by CMS that will provide additional clarification.

Comment: A few commenters indicated their support for requiring ESRD facilities to develop training and testing programs. The commenters stated that given the often medically fragile population that ESRD facilities serve and the risk of service disruption during an emergency, it would be beneficial for these facilities to train their staff and educate their patients regarding steps they can take to prepare themselves for emergency situations. A commenter expressed support while also reiterating that existing requirements for ESRD facilities require staff to be trained in emergency procedures. A commenter also expressed their support for allowing ESRD facilities to initiate a facility based mock drill in the absence of a community drill since participation in a community disaster drill has been difficult at times.

Response: We thank these commenters for their support and agree that emergency preparedness training and testing will benefit not only the staff of the ESRD facilities, but will also have a positive impact on the patients that they serve. We also encourage ESRD facilities to be proactive on preparing for emergencies. For example, it is essential that dialysis patients and their caregivers have all of their essential documentation, such as their doctor's orders or scripts, medical history, etc.

Comment: A commenter noted that with advance notice many dialysis patients can evacuate and find shelter with families and friends. However, they many have difficulty getting to another dialysis facility due to problems with transportation. The commenter did acknowledge that providing or arranging for transportation is beyond the scope of individual dialysis facilities, but they believed it should be addressed at a regional level.

Response: We agree with the commenter that transportation may be a problem for some dialysis patients that need to evacuate and that arranging for transportation in other areas is beyond the scope of responsibility for individual dialysis facilities. However, these facilities are required to provide emergency preparedness patient training, which includes instructions on what to do if the geographic area in which the dialysis facility is located must be evacuated (§ 494.62(d)(3)). We expect that instructions on who to contact for assistance would be included in that training.

Comment: Some commenters questioned our proposed requirement for policies and procedures that address having a process by which the staff could confirm that emergency equipment, including emergency drugs, were on the premises at all times and immediately available (§ 494.62(b)(9)). A commenter stated that this requirement concerns clinical practice policies that are outside the purview of emergency preparedness. They noted that while the needs of an individual patient in an emergency may require that the facility enact it emergency response plans, that the needs of an individual patient would not require the activation of the facility's emergency preparedness plan. Another commenter questioned if we would be providing a list of emergency drugs and specifying the quantities of those drugs that the dialysis facility would be expected to have at their facility.

Response: We disagree with commenter on this requirement being beyond the scope of this regulation. We are not attempting to regulate clinical practice. This section only requires that the staff have a process to ensure that emergency equipment is on the premises and available during an emergency. While we have listed some basic emergency equipment that should be available during any care-related emergency, it is the facility's responsibility to determine what emergency equipment it needs to have available. In addition, dialysis facilities need to be able to manage care-related emergencies during an emergency when other assistance, such as EMTs and ambulances, may not be immediately available to them. This final rule does not contain any specific list of emergency drugs or specify any quantities of drugs to have at a facility. That is beyond the scope of this rule. After this rule is finalized, there may be additional sub-regulatory guidance concerning this requirement.

Comment: Some commenters requested clarification on the requirement about having policies and procedures that address the role of the dialysis facility under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials (§ 494.62(b)(7)). A commenter inquired about nurses using protocols and what was CMS guidance on this. Another commenter thought that the requirement was vague and stated that further guidance was needed. This commenter noted that providers may request waivers and that facilities were unlikely to have a policy beyond either the facility's statement that they would comply with the waiver or a procedure on how to request a waiver.

Response: We believe that these issues are more appropriately addressed in sub-regulatory guidance. After this final rule is published, further guidance will be provided on how facilities should comply with this requirement.

Comment: A commenter suggested revising our proposed requirement for dialysis facilities to have policies and procedures that address "(6) The development of arrangements with other dialysis facilities or other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to dialysis facility patients." That commenter suggested modifying the language to read "multiple prearrangements with other dialysis facilities . . ."

Response: We disagree with the commenter. The proposed requirement uses the plural, "arrangements." We believe that clearly indicates that dialysis facilities are expected to have more than one arrangement with other facilities to maintain continuity of services to their patients. Thus, we will be finalizing the requirement as proposed.

Comment: A commenter suggested that dialysis facilities, as well as other providers, have a requirement to use volunteer management registries. Another commenter was supportive of ESRD facilities using the Medical Reserve Corps (MRC) and the Emergency System for Advance Registration of Volunteer Health Professional (ESAR–VHP) as discussed in the hospital section of the proposed rule (78 FR 79097).

Response: We are finalizing the requirement that is set forth in § 494.62(b)(5) that dialysis facilities have policies and procedures that address the use of volunteers in an emergency or other emergency staffing strategies, including a process and role for integration of state and federally designated healthcare professionals to address surge needs during an emergency. We believe that each facility needs the flexibility to determine how they should use volunteers during an emergency. If the facility is located in a state where there is a volunteer registry, that is certainly a valuable resource for any healthcare facility and we would encourage the use of that registry. However, we do not believe that this should be a requirement in this final rule. We also agree with the other commenter and encourage dialysis facilities to utilize assistance from the MRC and ESAR–VHP.

Comment: Some commenters noted that we did not require dialysis facilities to provide basic subsistence needs for their staff and patients during an emergency. A commenter agreed with not requiring the provision of subsistence needs. However, another commenter requested clarification on why this was not a requirement for dialysis facilities and recommended requiring subsistence need for at least a short period of time.

Response: We continue to believe that it is not appropriate to require that dialysis facilities provide subsistence needs for either their staff or patients. Based on our experience with dialysis facilities, we expect that most facilities would discharge any patients in their facility as soon as possible if they are unable to provide services. Therefore, requiring subsistence needs should not be necessary. However, we want to emphasize that the requirements in this final rule are the minimum requirements that dialysis facilities must meet to participate in the Medicare program. Every facility must develop and maintain its own emergency plan based on its risk assessment as required by § 494.62(a). Based on their risk assessment, any dialysis facility could decide that it should provide subsistence needs and for what duration.

Comment: A commenter noted that implementing the requirement for a dialysis facility to track staff and patients during and after an emergency include routine calls with the Kidney Community Emergency Response (KCER). KCER is a part of the Network Coordinating Center (NCC) that works with all 18 of the ESRD networks. KCER is the leading authority on emergency preparedness and response for the ESRD Network community with leadership and management delegated to the KCER staff under authority and direction of CMS.

Response: We agree with the commenter that KCER is an essential resource for the ESRD community. We recommend that dialysis facilities utilize this resource in their emergency preparedness activities. However, we believe that any specific requirements concerning communications in the ESRD community should be established in sub-regulatory guidance.

Comment: Concerning our proposed requirement for dialysis facilities to have policies and procedures for a system to track the location of staff and patients in the dialysis facility's care both during and after the emergency, a commenter stated that it would be reasonable for CMS to propose specific technology standards to make compatibility with electronic medical records (EMR) systems a reality. The commenter noted that reliance on print records is tenuous at best and this is associated with quick onset of an emergency.

Response: We acknowledge that EMRs would be very helpful in transitions in care and in locating patients. However, the specific technology standards for an EMR system suggested by the commenter are beyond the scope of this final rule.

Comment: A commenter believed that there was a contradiction between the preamble language ("[w]e do not propose to require ESRD facilities to provide basic subsistence needs for staff and patients, whether they evacuate or shelter in place, including food, water and medical supplies . . . (78 FR 79116)) and the requirement in proposed § 494.62(b)(3). The proposed section required dialysis facilities to have policies and procedures that addressed a means to shelter in place for patients, staff, and volunteers who remain in the facility. The commenter recommended that we provide further clarity and guidance on what is expected in the rule.

Response: We apologize for any confusion. However, in the language cited by the commenter, we were stating that we were not proposing any requirement related to subsistence needs associated with evacuation or sheltering in place, not that we were not proposing a requirement for the dialysis facility to have policies and procedures that address sheltering in place. We are finalizing § 494.62(b)(3) as proposed.

Comment: A commenter disapproved of allowing a one-year exemption from the requirement for a full-scale exercise if the facility experienced an actual emergency that required activation of their emergency plan. The commenter noted that appropriate and frequent activation are key to an emergency management plan success and that early but unnecessary plan activation is better than a needed but future activation. The best training tool for familiarizing the leadership and staff in emergency procedures is through experiencing actual plan activation.

Response: We agree that emergency plans must be activated for staff and the leadership to both get experience with the emergency procedures and test the plan. For that reason, we are finalizing the requirements for training and testing the emergency plan. However, we also believe that any facility that has had to activate their plan due to an actual emergency meets the requirements in this final rule and requiring another full-scale drill would be burdensome. Therefore, we are finalizing the exemption contained in § 494.62(d)(2)(i) as proposed.

Comment: A commenter wanted more specificity concerning the federal law(s) that dialysis facilities would be required to comply with in accordance with proposed § 494.62(c). The commenter wanted us to specifically state the federal law(s) to which the dialysis facilities would need to comply.

Response: Federal laws, as well as state and local laws, can be modified by the appropriate legislative bodies and executives at any time. In addition, dialysis facilities are already required to comply with the applicable federal, state, and local laws and regulations that pertain to both their licensure and any other relevant health and safety requirements (§ 494.20). Since the requirements we are finalizing are in the dialysis facilities' CfC, these facilities must already comply with all of the applicable federal, state, and local law and regulation concerning their licensure and health and safety standards and are responsible for knowing those laws and regulations. Thus, we are finalizing § 494.62(c) as proposed.

Comment: A commenter noted that we, as well as other HHS documents, suggest utilizing healthcare coalitions and that more descriptive terminology would be necessary to indicated at what level facilities and the Networks should be expected to act with emergency management at all of those levels.

Response: Commenting on other HHS documents is beyond the scope of this final rule. We have encouraged the providers and suppliers covered by this final rule to form and work with healthcare coalitions or both. However, that would be their choice, it is not required. In addition, since coalitions may be organized in different ways, it would be difficult to provide specific requirements on how providers and suppliers are to interact with them. Therefore, we do not believe it is appropriate to provide specific guidance or requirements on how dialysis facilities are to interact with coalitions.

Comment: A commenter believed that dialysis facilities and the ESRD Networks should be provided funding for the equipment that would be needed to comply with the requirement for a communication plan (§ 494.62(c)). The commenter specifically proposed funding for cellular devices and satellite communications technology for the ESRD Networks and GETS/WPS to ensure communications between providers and emergency management resources providing direction during emergencies.

Response: This rule finalizes the emergency preparedness requirements for dialysis facilities in § 494.62 of the ESRD CfCs. Dialysis facilities must comply with all of their CfCs to be certified by Medicare and must do so within the payments they received from Medicare.

Comment: A commenter notes that the proposed rule allowed for an exemption from an exercise after plan activation (proposed § 494.62(d)(2)). They recommended that it would be necessary for at least one component of the emergency plan specify what action(s) constitute activation of the plan.

Response: We agree with the commenter. Although it is not a specifically required component of the emergency plan, we do believe that each plan should indicate under what circumstances it would be deemed to be activated.

Comment: A commenter stated that we had erroneously attributed some type of collective authority and emergency assistance ability to the ESRD Networks. These are administrative governing bodies and liaisons with the federal government. They stated that the increased responsibilities imposed on the dialysis facilities by this rule would result in confusion within the ESRD community.

Response: We understand the commenter's concerns. However, we will be providing further sub-regulatory guidance after publication of this final rule. The guidance should provide more specific guidance for the ESRD community on how to comply with the requirements in this final rule.

After consideration of the comments we received on these provisions, and the general comments we received on the proposed rule, as discussed earlier and in the hospital section (section II.C. of this final rule), we are finalizing the proposed emergency preparedness requirements for ESRD facilities with the following modifications:

- Revising the introductory text of § 494.62 by adding the term "local" to clarify that dialysis facilities must also comply with local emergency preparedness requirements.
- Revising § 494.62(a)(4) by deleting the term "ensuring" and replacing the term "ensure" with "maintain."
- Revising § 494.62(b)(1) by clarifying that tracking during and after the emergency applies to on-duty staff and sheltered patients. We have also revised paragraph (b)(1) to provide that if on-duty staff and sheltered patients are relocated during the emergency, the dialysis facility must document the specific name and location of the receiving facility or other location.
- Revising § 494.62(b)(4) to change the phrase "ensures records are secure and readily available" to "secures and maintains availability of records."
- Revising § 494.62(b)(6) to replace the term "ensure" with "maintain."
- Revising § 494.62(b)(8) to delete the phrase "a process to ensure that" and replacing the term with "How."
- Revising § 494.62(b)(9) to delete the phrase "ensuring that" and replacing it with the term "by which the staff can confirm."
- Revising § 494.62(c), by adding the term "local" to clarify that the dialysis facility must develop and maintain an emergency preparedness communication plan that also complies with local laws.
- Revising § 494.510(c)(5) to clarify that the dialysis facility must develop a means, in the event of an evacuation, to release patient information, as permitted under 45 CFR 164.510(b)(1)(ii).
- Revising § 494.62(d) by adding that each dialysis facility's training and testing program must be based on the dialysis facility's emergency plan, risk assessment using an all hazards approach, policies and procedures, and communication plan.
- Revising § 494.62(d)(1)(iii) to replace the phrase "ensure that staff can demonstrate knowledge" to "demonstrate staff knowledge."
- Revising § 494.62(d)(2)(i) by replacing the term "community mock disaster drill" with "full-scale exercise."
- Revising § 494.62(d)(2)(ii) to allow a dialysis facility to choose the type of exercise it will conduct to meet the second annual testing requirement.
- Adding § 494.62(e) to allow a separately certified dialysis facilities within a healthcare system to elect to be a part of the healthcare system's emergency preparedness program.

III. Provisions of the Final Regulations

A. Changes Included in the Final Rule

In this final rule, we are adopting the provisions of the December 27, 2013 proposed rule (78 FR 79082) with the following revisions:

- For all provider and supplier types, we are making a technical revision to clarify that facilities must also coordinate with local emergency preparedness systems.
- For RNHCIs, inpatient hospices, CAHs, ASCs, and hospitals, we are removing the requirement for facilities to track all staff and patients after an emergency and clarifying that in the event on-duty staff and sheltered patients are relocated during an emergency, the provider/supplier must document the specific name and location of the receiving facility or other location for staff and patients who leave the facility during the emergency.
- For home based hospices and HHAs, we are removing the tracking requirement and requiring that in the event there is an interruption in services during or due to an emergency, the provider must have policies in place for following up with on-duty staff and patients to determine services that are still needed. In addition, they must inform state and local officials of any on-duty staff or patients that they are unable to contact.
- For ESRD facilities, CMHCs, LTC facilities, ICF/IIDs, PACE organizations, PRTFs, and OPOs we are clarifying that tracking during and after the emergency applies to on-duty staff and sheltered patients. We have also revised the regulations to provide that if on-duty staff and sheltered patients are relocated during the emergency, the facility must document the specific name and location of the receiving facility or other location.
- We did not propose a tracking requirement for CORFs, RHCs, FQHCs, transplant centers, and Organizations and have not made any revisions regarding tracking for these facilities in this final rule.
- For ASCs and HHAs, we are removing the requirement that ASCs and HHAs develop arrangements with other ASCs/HHAs and other providers to receive patients in the event of limitations or cessation of operations to ensure the continuity of services to patients.
- For ASCs and HHAs, we are removing the requirement that the communication plan include the names and contact information for other ASCs/HHAs.
- For all provider and supplier types, we are making a technical revision to clarify that facilities must develop and maintain an emergency preparedness communication plan that also complies with local law.
- For RNHCIs, ASCs, hospices, PRTFs, PACE organizations, hospitals, LTC facilities, ICF/IIDs, CAHs, CMHCs, and dialysis facilities, we are clarifying that these provider and supplier types must have a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).
- For all provider and supplier types with the exception of RNHCIs, OPOs, and transplant centers, we are revising testing requirements by replacing the term "community mock disaster drill" with "full-scale exercise."
- For ASCs only, we are removing the requirement for participation in a community-based testing exercise and revising the requirement to only require ASCs to conduct an individual, facility-based full scale testing exercise.
- For all provider and supplier types with the exception of RNHCIs, OPOs, and transplant centers, we are revising testing requirements to allow each facility to choose the type of exercise they must conduct to meet the second annual testing requirement.
- For hospitals, CAHs, and LTC facilities, we are revising emergency and standby power system requirements by removing the requirement for an additional 4 hours of generator testing and clarifying that a facility must meet the requirements of NFPA® 99 2012 edition and NFPA® 110, 2010 edition.
- For hospitals, CAHs, and LTC facilities, we are revising emergency and standby power system requirements by removing the requirement that a facility must maintain fuel onsite and clarifying that facilities must have a plan to maintain operations unless the facility evacuates.
- For all provider and supplier types, we are adding a separate standard to the regulations text that will allow a separately certified healthcare facility within a healthcare system to elect to be a part of the healthcare systems unified emergency preparedness program.

B. Incorporation by Reference

In this final rule, we are incorporating by reference the NFPA 101® 2012 edition of the LSC, issued August 11, 2011, and all Tentative Interim Amendments issued prior to April 16, 2014; the NFPA 99® 2012 edition of the Health Care Facilities Code, issued August 11, 2011, and all Tentative Interim Amendments issued prior to April 16, 2014; and the NFPA 110 ® 2010 edition of the Standard for Emergency and Standby Power

Systems(including Tentative Interim Amendments to chapter 7), issued August 6, 2009.

- NFPA® 99, Health Care Facilities Code, 2012 edition, issued August 11, 2011.
  ++ TIA 12–2 to NFPA® 99, issued August 11, 2011.
  ++ TIA 12–3 to NFPA® 99, issued August 9, 2012.
  ++ TIA 12–4 to NFPA® 99, issued March 7, 2013.
  ++ TIA 12–5 to NFPA® 99, issued August 1, 2013.
  ++ TIA 12–6 to NFPA® 99, issued March 3, 2014.
- NFPA® 101, Life Safety Code, 2012 edition, issued August 11, 2011;
  ++ TIA 12–1 to NFPA® 101, issued August 11, 2011.
  ++ TIA 12–2 to NFPA® 101, issued October 30, 2012.
  ++ TIA 12–3 to NFPA® 101, issued October 22, 2013.
  ++ TIA 12–4 to NFPA® 101, issued October 22, 2013.
- NFPA® 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

The materials that are incorporated by reference are reasonably available to interested parties and can be inspected at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, *www.nfpa.org,* 1.617.770.3000. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the **Federal Register** to announce the changes.

The NFPA 101® 2012 edition of the LSC (including the TIAs) provides minimum requirements, with due regard to function, for the design, operation and maintenance of buildings and structures for safety to life from fire. Its provisions also aid life safety in similar emergencies.

The NFPA 99® 2012 edition of the Health Care Facilities Code (including the TIAs) provides minimum requirements for health care facilities for the installation, inspection, testing, maintenance, performance, and safe practices for facilities, material, equipment, and appliances, including other hazards associated with the primary hazards.

The NFPA 110® 2010 edition of the Standard for Emergency and Standby Power Systems (including the TIAs) provides minimum requirements for the installation, maintenance, operation, and testing requirements as they pertain to the performance of the emergency power supply system (EPSS).

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. Factors Influencing ICR Burden Estimates

Please note that under this final rule, a hospital's ICRs will differ from the ICRs of other Medicare or Medicaid provider and supplier types. We have calculated the ICR for each provider and supplier separately and have included a chart summarizing the burden at the end of each section. A significant factor in the burden for each provider or supplier type will be whether the type of facility provides inpatient services, outpatient services, or both. Moreover, even where the regulatory requirements are the same, certain factors will greatly affect the burden for different providers and suppliers, such as the size and location of the provider or supplier, whether or not they participate in any type of network, and whether they already have a substantial emergency preparedness program.

We have determined that the development of an emergency plan is more labor intensive than conducting the risk assessment for a few reasons. In general, the risk assessment process requires following a checklist and/or filling out a table (see: *https://asprtracie.hhs.gov/documents/tracie-evaluation-of-HVA-tools.pdf* for a set of examples), whereas planning is a more comprehensive process that requires individual expertise, identifying mitigation options to problems, and documenting policies and procedures to mitigation potential challenges that may arise depending on the identified in their risk assessment. We also reference numerous resources in the preamble that are available for use by providers and suppliers to help develop their risk assessments. Also, in the final rule, we allow providers and suppliers who are part of integrated health systems to develop one risk assessment and we encourage them to work with their community health coalitions in doing so. As a result, we expect that it will take more time to complete the emergency plan in comparison to the amount of time it will take to conduct a risk assessment as the emergency plan must be unique to the specific facility to which it applies.

In each section, where possible, we provide information regarding the characteristics which drive burden for each provider and supplier type. Current Medicare or Medicaid regulations for some providers and suppliers include requirements similar to those in this regulation. For example, existing regulations for RNHCIs and dialysis facilities require both types of facilities to have written disaster plans that address emergencies (42 CFR 403.742(a)(4) and 42 CFR 494.60(d)(4), respectively).

We have determined that the time required to conduct an annual review and update of the emergency preparedness plan is dependent upon whether there are existing emergency preparedness requirements for the providers and suppliers. We believe that the providers and suppliers with existing emergency preparedness requirements have some sort of an emergency preparedness plan that is updated at least annually based on current standards of practice. For these providers and suppliers, no additional burden has been assigned for the annual review and update of the emergency preparedness plan. The following providers and suppliers currently have emergency preparedness requirements: RNCHIs, ASCs, PACE organizations, Hospitals, ICF/IIDs, HHAs, CORFs, CAHs, Organizations, RHCs, FQHCs, inpatient hospice, and ESRD facilities. For those providers and suppliers who do not have existing emergency preparedness requirements, we believe that it is less likely that there is an emergency preparedness plan that is reviewed and updated annually. For these providers and suppliers, we estimate that the time it takes to review and update the plan annually is equal to one-third of the amount of time it takes to develop their emergency preparedness plan. The following providers and suppliers currently do not have emergency preparedness requirements: CMHCs, OPOs, PRTFs and outpatient hospices.

Furthermore, some accrediting organizations (AOs) that have CMS-approved accreditation programs for Medicare providers and suppliers have emergency preparedness standards. Those organizations are: The Joint Commission (TJC), the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP), the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC), the American Association for Accreditation for Ambulatory Surgery Facilities, Inc. (AAAASF), and Det Norske Veritas (DNV) GL—Healthcare (DNV GL). Each of these AOs has deeming authority for different types of facilities; for example, TJC has comprehensive emergency preparedness requirements for hospitals. Thus, as noted in the hospital discussion later in this section, we anticipate that TJC-accredited hospitals will have a smaller burden associated with this final rule than many other providers or suppliers.

In addition, many facilities already have begun preparing for emergencies. According to a study by Niska and Burt, virtually all hospitals already have plans to respond to natural disasters (Niska and Shimizu I. "Hospital preparedness for emergency response: United States, 2008." National Health Statistics Reports. (2011): 1–14).

Hospitals, as well as other healthcare providers, also receive grant funding for disaster or emergency preparedness from the federal and state governments, as well as other private and non-profit entities. However, we were unable to determine the amount of funding that has been granted to hospitals, the number of hospitals that received funding, or whether that funding will continue in a predictable manner. We also do not know how the hospitals spent this funding. Therefore, in determining the burden for this final rule, we did not take into account any funding a hospital or other healthcare provider might have received from sources other than Medicare or Medicaid.

B. Sources of Data Used in Estimates of Burden Hours and Cost Estimates

We obtained the data used in this discussion on the number of the various Medicare and Medicaid providers and suppliers from Medicare's Certification and Survey Provider Enhanced Reporting (CASPER) as of June 2016, unless indicated otherwise. We have not included data for healthcare facilities that are not Medicare or Medicaid certified.

Unless otherwise indicated, we obtained all salary information for the different positions identified in the following assessments from the May 2014 National Occupational Employment and Wage Estimates, United States by the Bureau of Labor Statistics at *http://www.bls.gov/oes/current/oes_nat.htm*. In the proposed rule we added a 30 percent increase for overhead and benefits. For the final rule, we have calculated the estimated hourly rates in this final rule based upon the national mean salary for that particular position to include a 100 percent increase for overhead and benefits. Where we were able to identify positions linked to specific providers or suppliers, we used that compensation information. However, in some instances, we used a general position description, such as director of nursing, or we used information for comparable positions. For example, we were not able to locate specific information for physicians who practice in hospices. However, since hospices provide palliative care, we used the compensation information for physicians who work in specialty hospitals.

Salary may be affected by the rural versus urban locations. For example, based on our experience with CAHs, they usually pay their administrators less than the mean hourly wage for Health Service Managers in general medical and surgical hospitals. Thus, we considered the impact of the rural nature of CAHs to estimate the hourly wage for CAH administrators and calculated total compensation by adding in an amount for fringe benefits. Many healthcare providers and suppliers could reduce their burden by partnering or collaborating with other facilities to develop their emergency management plans or programs. Due to a lack of data, we did not consider this in our burden estimates. In estimating the burden associated with this final rule, we took into consideration the many free or low cost emergency management resources healthcare facilities have available to them and assume that many providers will use only these resources in order to meet the requirements of this rule. If we feel an organization may hire a consultant or contractor, we have indicated such. Following is a list of some of the available resources:

Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR).

- *http://asprtracie.hhs.gov/* Technical Resources, Assistance Center, and Information Exchange (TRACIE).
- *http://www.phe.gov/about.*

Health Resources and Services Administration-Emergency Preparedness and Continuity of Operations.

- *http://www.hrsa.gov/emergency/.*

Centers for Medicare and Medicaid Services (CMS).

- *www.cms.hhs.gov/Emergency/.*

Centers for Disease Control and Prevention—Emergency Preparedness & Response.

- *www.emergency.cdc.gov.*

Food and Drug Administration (FDA)—Emergency Preparedness and Response.

- *http://www.fda.gov/EmergencyPreparedness/default.htm.*

Substance Abuse and Mental Health Services Administration (SAMHSA)—Disaster Readiness and Response.

- *http://www.samhsa.gov/Disaster/.*

National Institute for Occupational Safety and Health (NIOSH)—Business Emergency Management Planning.

- *www.cdc.gov/niosh/topics/emres/business.html.*

Department of Labor (DOL), Occupational Safety and Health Administration (OSHA)—Emergency Preparedness and Response.

- *www.osha.gov/SLTC/emergencypreparedness.*

Federal Emergency Management Agency (FEMA)—State Offices and Agencies of Emergency Management—Contact Information.

- *http://www.fema.gov/about/contact/statedr.shtm.*
- *http://www.fema.gov/plan-prepare-mitigate.*

Department of Homeland Security (DHS).

- *http://www.dhs.gv/training-technical-assistance.*

Comment: Multiple commenters believe that we underestimated the amount of time and work it will take for many providers and suppliers to come into compliance with our proposed requirements. Specifically, some commenters expressed that we did not truly capture what updating policies and procedures will entail. The commenters explained that updating policies and procedure will go beyond having meetings, drafting revisions, and obtaining approvals. They expressed that updating policies and procedures would also involve researching alternatives, assessing costs that may be involved, reviewing potential changes with affected employees, implementing the changes, and training staff and testing outcomes.

Response: We appreciate the commenter's feedback and understand their concerns. As discussed earlier in the preamble, we recognize the level of work it will take for facilities to come into compliance with these requirements. While we understand that updating policies and procedures can involve many tasks and that for some facilities emergency preparedness requirements may be new. We believe that periodically reviewing and updating policies and procedures is a standard business practice for healthcare facilities since they must comply with applicable federal, state, and local laws, regulations, and ordinances that periodically change. Adding disaster related policies may be a new task for some, but the process of updating policies and procedures will not be a brand new burden. As part of an annual review and update, staff are required to be trained and be familiar with many policies and procedures in the operation of their facility and are held responsible for knowing these requirements. Annual reviews help to refresh these policies and procedures which would include any revisions to them based on the facility experiencing an emergency or as a result of a community or natural disaster. Basic contact information and procedures could be updated during an annual review. We would not expect that an annual review would be an extensive overhaul of their EP plan. Healthcare facilities routinely revise and update policies and operational procedures to ensure that they are operating based on best practices.

Therefore, we accounted for the staff time that will be involved to review and update current policies and procedures for alignment with these emergency preparedness requirements.

Comment: Some commenters believe that we incorrectly estimated the salaries of the staff involved in meeting the requirements. A commenter questioned whether CMS could use average wages by region for determining the salaries, rather than national average wages. The commenter believes that the wages used in the proposed rule were low for their area, therefore underestimating the estimates for conducting the risk assessment and developing the emergency plan.

Response: As indicated in the proposed rule, we obtained all salary information for the different positions identified in the following assessments from the National Occupational Employment and Wage Estimates, United States by the Bureau of Labor Statistics (BLS). We calculated the estimated hourly rates based upon the national mean salary for that particular position, including a 30 percent increase for overhead and benefits. In this final rule, we have updated the salary data as indicated by the BLS data. The final rule salaries include a 100 percent increase for overhead and benefits. Where we were able to identify positions linked to specific providers or suppliers, we used that compensation information. However, in some instances, we used a general position description, such as director of nursing, or we used information for comparable positions.

Comment: A commenter believes that we miscalculated the time and expense required in planning and carrying out a community-based drill. The commenter believes that while most unaccredited providers and suppliers probably would not be starting from scratch with regard to drills and exercises, our description of the tasks and burdens associated with organizing a drill is still insufficient. The commenter believes that we did not provide a thorough explanation of what the emergency drill process would actually entail. The commenter points out that planning would include tasks such as contacting other providers and community emergency response agencies, convening with this group on a regular basis, and writing the hospital's part of the exercise. They also suggest that participating in the drill would include recruiting volunteers, informing patients about the drill, and obtaining financial approval to conduct the drills. The commenter believes that given all of this, it could more realistically take six months to a year to plan and carry out a comprehensive emergency drill and urges CMS to revise our estimates to more accurately reflect the time and resources involved.

Response: The regulation would require some providers to participate in a community-based training exercise where available. We are not requiring facilities to plan and execute a community-wide exercise, only participate to the extent their facility would contribute in an emergency situation if the whole community/town is impacted. When a community-based exercise is not accessible, facilities would conduct a facility-based training. As the commenter pointed out, we did not provide prescriptive emergency exercises and drills. Instead, we provided resources that facilities can utilize in developing their drills and exercises. The time estimates we used to calculate the burden associated with conducting a drill for each provider and supplier were our best estimates for the activity. Our estimates serve as a baseline for the time it will take to implement the task, understanding that the actual time and task involved will vary for each individual facility based on the unique circumstances of each facility. We provided a time estimate for the activities that, at a minimum, each facility will have to take into consideration when conducting a community drill.

Comment: We received conflicting comments regarding the staff positions that will be involved in the activities of developing the emergency preparedness programs. For example, one commenter indicated that in addition to an administrator and director of nursing, a plant manager and food service manager will also need to be included in the process of developing the plan and conducting the risk assessment. Other commenters indicated that the majority of the burden associated with developing plans, updating policies and procedures, and facilitating/planning trainings and testing will fall on the administrator.

Response: Based upon our experience with the various providers and suppliers, we determined the staff positions that would likely be involved in complying with the varying requirements for the different providers and suppliers. The actual individuals who are involved in the activities needed to comply with the requirements in this final rule will vary based on the unique circumstances of each individual healthcare facility. Our estimates provide an overall idea of the necessary staff positions involved, but we note that ultimately the actual individuals involved will be determined by the individual facility. We have listed personnel that would address various components of the EP requirements in both the ICR and RIA sections of the rule.

C. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 403.748)

Section 403.748(a) will require RNHCIs to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. We proposed that the plan must meet the requirements specified at § 403.748(a)(1) through (4). We will discuss the burden for these activities individually beginning with the risk assessment requirement in § 403.748(a)(1).

The current RNHCI CoPs already require RNHCIs to have a written disaster plan that addresses "loss of power, water, sewage, and other emergencies" (42 CFR 403.742(a)(4)). In addition, the CoPs also require RNHCIs to include measures to evaluate facility safety issues, including physical environment, in their quality assessment and performance improvement (QAPI) program (42 CFR 403.732(a)(1)(vi)). We expect that all RNHCIs have considered some of the risks likely to happen in their facility. However, we expect that all RNHCIs will need to review any existing risk assessment and perform the tasks necessary to ensure their assessment is documented and utilize a facility-based and community based all-hazards approach.

We have not designated any specific process or format for RNHCIs to use in conducting their risk assessment because we believe they need the flexibility to determine how best to accomplish this task. However, we expect that they will obtain input from all of their major departments in the process of developing their risk assessments.

Based on our experience with RNHCIs, we expect that complying with this requirement will require the involvement of an administrator, the director of nursing, and the head of maintenance. It is important to note that RNHCIs do not provide medical care to their patients. Depending upon the state in which they are located, RNHCIs may not be licensed and may not have licensed or certified staff. RNHCIs do not compensate their staff at the same level we have used to determine the burden for other healthcare providers and suppliers. Therefore, for the purpose of estimating the burden, we have used lower hourly wages for the RNHCI staff than for other providers and suppliers whose staff must comply with licensing and certification standards.

We expect that to perform a risk assessment, the RNHCI's administrator (2 hours), the director of nursing (5 hours), and the head of maintenance (2 hours) will attend an initial meeting; review relevant sections of the current risk assessment; prepare comments; attend a follow-up meeting; perform a final review, and approve the risk assessment. We expect that the director of nursing will coordinate the meetings, review and critique the current risk assessment, coordinate comments, develop the new risk assessment, and ensure that it is approved.

We estimate that it will require 9 burden hours for each RNHCI to complete the risk assessment at a cost of $366. There are 18 RNHCIs. Therefore, it will require an estimated 162 annual burden hours (9 burden hours for each RNHCI × 18 RNHCIs) for all 18 RNHCIs to comply with this requirement at a cost of $6,588 ($366 estimated cost for each RNHCI × 18 RNHCIs).

TABLE 1—TOTAL COST ESTIMATE FOR A RNHCI TO CONDUCT A RISK ASSESSMENT

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$72	2	$144
Director of Nursing	34	5	170
Head of Maintenance	26	2	52
Total	....	9	366

After conducting a risk assessment, RNHCIs will need to review, revise, and, if necessary, develop new sections for their emergency plans. The current RNHCI CoPs require RNHCIs to have a written disaster plan for emergencies (§ 403.742(a)(4)). However, based on our experience with RNHCIs, their plans likely will address only evacuation from their facilities. We expect that all RNHCIs will need to review, revise, and develop new sections for their plans.

We expect that the same individuals who were involved in developing the risk assessment will be involved in developing the emergency preparedness plan. However, we expect that it will require substantially more time to complete the plan than to complete the risk assessment. We estimate that complying with this requirement will require 12 burden hours for each RNHCI at a cost of $498. Therefore, for all 18 RNHCIs to comply with these requirements will require an estimated 216 burden hours (12 burden hours for each RNHCI × 18 RNHCIs) at a cost of $8,964 ($498 estimated cost for each RNHCI × 18 RNHCIs).

TABLE 2—TOTAL COST ESTIMATE FOR A RNHCI TO DEVELOP AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$72	3	$216
Director of Nursing	34	6	204
Head of Maintenance	26	3	78
Totals	....	12	498

Under this final rule, RNHCIs will be required to review and update their emergency preparedness plans at least annually. For the purpose of determining the burden associated with this requirement, we will expect that RNHCIs already review their plans annually. Based on our experience with Medicare providers and suppliers, healthcare facilities have a compliance officer or other staff member who periodically reviews the facility's program to ensure that it complies with all relevant federal, state, and local laws, regulations, and ordinances. While this requirement is subject to the PRA, we expect that complying with the requirement for an annual review of the emergency preparedness plan will constitute a usual and customary business practice as defined in the implementing regulation of the PRA at 5 CFR 1320.3(b)(2). Therefore, we have not assigned a burden.

Section 403.748(b) will require RNHCIs to develop and implement emergency preparedness policies and procedures in accordance with their emergency plan based on the emergency plan set forth in paragraph (a), the risk assessment at paragraph (a)(1), and the communication plan at paragraph (c). These policies and procedures will have to be reviewed and updated at least annually. At a minimum, we proposed that the policies and procedures be required to address the requirements specified in § 403.748(b)(1) through (8). The RNHCIs will need to review their policies and procedures and compare them to their emergency plan, risk assessment, and communication plan. Most RNHCIs will need to revise their existing policies and procedures or develop new policies and procedures.

The current RNHCI CoPs require them to have written policies concerning their services (§ 403.738). Thus, some RNHCIs may have some emergency preparedness policies and procedures. However, based on our experience with RNHCIs, most of their emergency preparedness policies address only evacuation from the facility.

We expect that these tasks will involve the administrator, the director of nursing, and the head of maintenance. All three will need to review and comment on the RNHCI's current policies and procedures. The director of nursing will revise or develop new policies and procedures, as needed, ensure that they are approved, and compile and disseminate them to the appropriate parties. We estimate that it will require 6 burden hours for each RNHCI to comply with this requirement at a cost of $234. Thus, it will require 108 burden hours (6 burden hours for each RNHCI × 18 RNHCIs) for all 18 RNHCIs to comply with the requirements in § 403.748(b)(1) through (8) at a cost of $4,212 ($234 estimated cost for each RNHCI × 18 RNHCIs).

TABLE 3—TOTAL COST ESTIMATE FOR A RNHCI TO DEVELOP NEW POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$72	1	$72
Director of Nursing	34	4	136
Head of Maintenance	26	1	26
Totals		6	234

Section 403.748(c) will require RNHCIs to develop and maintain an emergency preparedness communication plan that complies with both federal and state law and must be reviewed and updated at least annually. We proposed that the communication plan include the information specified at § 403.748(c)(1) through (7). The burden associated with complying with this requirement will be the resources required to review and, if necessary, revise an existing communication plan or develop a new plan. Based on our experience with RNHCIs, we expect that these activities will require the involvement of the RNHCI's administrator, the director of nursing, and the head of maintenance. We estimate that complying with this requirement will require 4 burden hours for each RNHCI at a cost of $166. Thus, it will require an estimated 72 burden hours (4 burden hours for each RNHCI × 18 RNHCIs) at a cost of $2,988 ($166 estimated cost for each RNHCI × 18 RNHCIs).

TABLE 4—TOTAL COST ESTIMATE FOR A RNHCI TO DEVELOP A COMMUNICATION PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$72	1	$72
Director of Nursing	34	2	68
Head of Maintenance	26	1	26
Totals		4	166

We proposed that RNHCIs will also have to review and update their emergency preparedness communication plan at least annually. We believe that RNHCIs already review their emergency preparedness communication plans periodically. Thus, complying with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulation of the PRA at 5 CFR 1320.3(b)(2). Therefore, we have not assigned a burden.

Section 403.748(d) will require RNHCIs to develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually. We are proposing that a RNHCI meet the requirements specified at § 403.748(d)(1) and (2). Section 403.748(d)(1) will require RNHCIs to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, the RNHCI will have to provide training at least annually. Based on our experience, all RNHCIs have some type of emergency preparedness training program. However, all RNHCIs will need to compare their current emergency preparedness training programs to their risk assessments and updated emergency preparedness plans, policies and procedures, and communication plans and revise or, if necessary, develop new sections for their training programs.

We expect that complying with these requirements will require the involvement of the RNHCI administrator and the director of nursing. We estimate that it will require 7 burden hours for each RNHCI to develop an emergency training program at a cost of $314. Thus, it will require an estimated 126 burden hours (7 burden hours for each RNHCI × 18 RNHCIs) at a cost of $5,652 ($1855 estimated cost for each RNHCI × 18 RNHCI).

TABLE 5—TOTAL COST ESTIMATE FOR A RNHCI TO DEVELOP A TRAINING PROGRAM

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$72	2	$144

TABLE 5—TOTAL COST ESTIMATE FOR A RNHCI TO DEVELOP A TRAINING PROGRAM—Continued

Position	Hourly wage	Burden hours	Cost estimate
Director of Nursing	34	5	170
Totals		7	314

We are proposing that RNHCIs also review and update their emergency preparedness training and testing programs at least annually. Based on our experience with Medicare providers and suppliers, healthcare facilities have a compliance officer or other staff member who periodically reviews the facility's program to ensure that it complies with all relevant federal, state, and local laws, regulations, and ordinances. While this requirement is subject to the PRA, we expect that complying with this requirement will constitute a usual and customary business practice as defined in the implementing regulation of the PRA at 5 CFR 1320.3(b)(2). Therefore, we have not calculated an estimate of the burden.

Section 403.748(d)(2) will require RNHCIs to conduct a paper-based, tabletop exercise at least annually. The RNHCI must also analyze its response to and maintain documentation of all tabletop exercises and emergency events, and revise its emergency plan, as needed.

The burden associated with complying with this requirement will be the resources RNHCIs will need to develop the scenarios for the exercises and the necessary documentation. Based on our experience with RNHCIs, RNHCIs already conduct some type of exercise periodically to test their emergency preparedness plans. However, we expect that RNHCIs will not be fully compliant with our requirements. We expect that the director of nursing will develop the scenarios and required documentation. We estimate that these tasks will require 3 burden hours at a cost of $102 for each RNCHI. Based on this estimate, for all 18 RNHCIs to comply with these requirements will require 54 burden hours (3 burden hours for each RNHCI × 18 RNHCIs) at a cost of $1,836 ($102 estimated cost for each RNHCI × 18 RNHCI).

TABLE 6—TOTAL COST ESTIMATE FOR A RNHCI TO CONDUCT TRAINING EXERCISES

Position	Hourly wage	Burden hours	Cost estimate
Director of Nursing	$34	3	$102
Totals		3	102

TABLE 7—BURDEN HOURS AND COST ESTIMATES FOR ALL 18 RNHCIS TO COMPLY WITH THE ICRS CONTAINED IN § 403.748 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 403.748(a)(1)	0938–New	18	18	9	162	**	6,588	6,588
§ 403.748(a)(1)–(4)	0938–New	18	18	12	216	**	8,964	8,964
§ 403.748(b)	0938–New	18	18	6	108	**	4,212	4,212
§ 403.748(c)	0938–New	18	18	4	72	**	2,988	2,988
§ 403.748(d)(1)	0938–New	18	18	7	126	**	5,652	5,652
§ 403.748(d)(2)	0938–New	18	18	3	54	**	1,836	1,836
Totals		18	108		738			30,240

** The hourly labor cost is blended between the wages for multiple staffing levels.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 7.

D. ICRs Regarding Condition for Coverage: Emergency Preparedness (§ 416.54)

Section 416.54(a) will require ASCs to develop and maintain an emergency preparedness plan and review and update that plan at least annually. We proposed that the plan must meet the requirements contained in § 416.54(a)(1) through (4).

We will discuss the burden for these activities individually in this final rule beginning with the risk assessment requirement in § 416.54(a)(1). We expect that each ASC will conduct a thorough risk assessment. This will require the ASC to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. We expect that an ASC will consider its location and geographical area; patient population, including those with disabilities and other access and functional needs; and the type of services the ASC has the ability to provide in an emergency. The ASC also will need to identify the measures it must take to ensure continuity of its operation, including delegations and succession plans.

The burden associated with this requirement will be the time and effort necessary to perform a thorough risk assessment. As of June 2016, there are 5,485 ASCs. The current regulations covering ASCs include emergency preparedness requirements.

A significant factor in determining the burden is the accreditation status of an ASC. Of the 5,485 ASCs, 4,071 are non-accredited and 1,414 are accredited. Of the 1,414 accredited ASCs, we estimate that 491 are accredited by The Joint Commission (TJC), 731 by the AAAHC, and additional facilities are accredited by the AOA/HFAP or the AAAASF. The accreditation standards for these organizations vary in their requirements related to emergency preparedness. The AOA/HFAP's standards are very similar to the current ASC regulations. AAAASF does have some emergency preparedness requirements, such as requirements for responses or written protocols for security emergencies, for example, intruders and other threats to staff or patients; power failures; transferring patients; and emergency evacuation of the facility. However, the accreditation standards for both the AOA/HFAP and AAAASF will not significantly satisfy the ICRs contained in this final rule. Therefore, for the purpose of determining the burden imposed on ASCs by this final rule, we will include the ASCs that are accredited by both the AOA/HFAP and AAAASF with the non-accredited ASCs.

TJC and AAAHC's accreditation standards contain more extensive emergency preparedness requirements than the accreditation standards of either AOA/HFAP or AAAASF. For example, TJC standards contain requirements for risk assessments and an emergency management plan. AAAHC's standards include requirements for both internal and external emergencies and drills for the facility's internal emergency plan. Therefore, in discussing the individual burden requirements in this final rule, we will discuss the burden for the estimated 1,222 accredited ASCs by either the AAAHC or TJC (731 AAAHC-accredited ASCs + 491 TJC-accredited ASCs) separately from the remaining 4,263 (ASCs that are not accredited by an accrediting organization or accredited by the AOA/HFAP and AAAASF). For some requirements, only the TJC accreditation standards are significantly like those in the final rule. For those requirements, we will analyze the 491 TJC-accredited ASCs separately from the 4,994 non TJC-accredited ASCs (5,485 ASCs − 491 TJC-accredited ASCs).

For the purpose of determining the burden for the TJC-accredited ASCs, we used TJC's Comprehensive Accreditation Manual for Ambulatory Care: The Official Handbook 2008 (CAMAC). Concerning the requirement for a risk assessment in § 416.54(a)(1), in the chapter entitled "Management of the Environment of Care" (EC), ASCs are required to conduct comprehensive, proactive risk assessments (CAMAC, CAMAC Refreshed Core, January 2007, (CAMAC), TJC Standard EC.1.10, EP 4, p. EC–9). In addition, ASCs must conduct a hazard vulnerability analysis (HVA) (CAMAC, Standard EC.4.10, EP 1, p. EC–12). The HVA requires the identification of potential emergencies and the effects those emergencies could have on the ASC's operations and the demand for its services (CAMAC, p. EC–12). We expect that TJC-accredited ASCs already conduct a risk assessment that complies with these requirements. If there are any tasks these ASCs need to complete to satisfy the requirement for a risk assessment, we expect that the burden imposed by this requirement will be negligible. For the 491 TJC-accredited ASCs, the risk assessment requirement will constitute a usual and customary business practice. While this requirement is subject to the PRA, we expect that complying with this requirement will constitute a usual and customary business practice as defined in the implementing regulations of the PRA at 5 CFR 1320.3(b)(2). Therefore, we have not estimated the amount of regulatory burden For ASCs with accreditation from TJC.

For the purpose of determining the burden for the 731 AAAHC-accredited ASCs, we used the Accreditation Handbook for Ambulatory Health Care 2008 (AHAHC). The AAAHC standards do not contain a specific requirement for the ASC to perform a risk assessment. However, in discussing the requirement for drills, the AAAHC notes that such drills should be appropriate to the facility's activities and environment (AHAHC, Accreditation Association for Ambulatory Health Care, Inc., Core Standards, Chapter 8. Facilities and Environment, Element E, p. 37). Therefore, we expect that in fulfilling this core standard that the 731 AAAHC-accredited ASCs have performed some type of risk assessment. However, we do not expect that this will satisfy the requirement for a facility-based and community-based risk assessment that addresses the elements include in the AAAHC-accreditation for ASCs. Therefore, the 731 AAAHC-accredited ASCs will be included in the burden analysis with the ASCs that are non-accredited or are accredited by AOA/HFAP and AAAASF for the risk assessment requirement for 4,994 non TJC-accredited ASCs (5,485 total ASCs − 491 TJC-accredited ASCs).

We expect that all ASCs have already performed at least some of the work needed for a risk assessment. However, many probably have not performed a thorough risk assessment. Therefore, we expect that all non TJC-accredited ASCs will perform thorough reviews of their current risk assessments, if they have them, and revise them to ensure they have updated the assessments and that they have included all of the requirements in § 416.54(a).

We have not designated any specific process or format for ASCs to use in conducting their risk assessments because we believe that ASCs, as well as other healthcare providers and suppliers, need maximum flexibility in determining the best way for their facilities to accomplish this task. However, we expect healthcare facilities to, at a minimum; include input from all of their major departments in the process of developing their risk assessments. Based on our experience working with ASCs, we expect that conducting the risk assessment will require the involvement of an administrator and a registered nurse. We expect that to comply with the requirements of this section, both of these individuals will need to attend an initial meeting, review the current assessment, prepare their comments, attend a follow-up meeting, perform a final review, and approve the risk assessment. In addition, we expect that the quality improvement nurse will coordinate the meetings; perform an initial review of the current risk assessment; provide suggestions or a critique of the risk assessment; coordinate comments; revise the original risk assessment; develop any necessary sections for the risk assessment; and ensure that the appropriate parties approve the new risk assessment. We estimate that complying with this risk assessment requirement will require 8 burden hours for each ASC at a cost of $763. Based on that estimate, it will require 39,952 burden hours (8 burden hours for each ASC × 4,994 non TJC-accredited ASCs) for all non TJC-accredited ASCs to comply with this risk assessment requirement at a cost of $3,810,422 ($763 estimated cost for each ASC × 4,994 ASCs).

TABLE 8—TOTAL COST ESTIMATE FOR A NON-TJC ACCREDITED ASC TO CONDUCT A RISK ASSESSMENT

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$110	5	$550
Registered Nurse—Quality Improvement	71	3	213

TABLE 8—TOTAL COST ESTIMATE FOR A NON-TJC ACCREDITED ASC TO CONDUCT A RISK ASSESSMENT—Continued

Position	Hourly wage	Burden hours	Cost estimate
Total	....	8	763

After conducting the risk assessment, ASCs will be required to develop and maintain emergency preparedness plans in accordance with § 416.54(a)(1) through (4). All TJC-accredited ASCs must already comply with many of the requirements in § 416.54(a). All TJC-accredited ASCs are already required to develop and maintain a "written emergency management plan describing the process for disaster readiness and emergency management" (CAMAC, Standard EC.4.10, EP 3, EC–13). We expect that the TJC-accredited ASCs already have emergency preparedness plans that comply with these requirements. If there are any activities required to comply with these requirements, we expect that the burden will be negligible. Thus, for 491 TJC-accredited ASCs, this requirement will constitute a usual and customary business practice for these ASCs in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2). Therefore, we will not include this activity in the burden analysis for those ASCs.

AAAHC-accredited ASCs are required to have a "comprehensive emergency plan to address internal and external emergencies" (AHAC, Chapter 8. Facilities and Environment, Element D, p. 37). However, we do not believe that this requirement ensures compliance with all of the requirements for an emergency plan. We will include the 731 AAAHC-accredited ASCs in the burden analysis for this requirement.

We expect that the 4,994 non TJC-accredited ASCs have developed some type of emergency preparedness plan. However, under this final rule, all of these ASCs will have to review their current plans and compare them to the risk assessments they performed in accordance with § 416.54(a)(1). The ASCs will then need to update, revise, and in some cases, develop new sections to ensure that their plans incorporate their risk assessments and address all of the requirements. The ASC will also need to review, revise, and, in some cases, develop the delegations of authority and succession plans that ASCs determine are necessary for the appropriate initiation and management of their emergency preparedness plans.

The burden associated with this requirement will be the time and effort necessary to develop an emergency preparedness plan that complies with all of the requirements in § 416.54(a)(1) through (4). Based upon our experience with ASCs, we expect that the administrator and the quality improvement nurse who will be involved in the risk assessment will also be involved in developing the emergency preparedness plan. We estimate that complying with this requirement will require 11 burden hours for each ASC at a cost of $937. Therefore, based on that estimate, for the 4,994 non TJC-accredited ASCs to comply with the requirements in this section will require 54,934 burden hours (11 burden hours for each non TJC-accredited ASC × 4,994 non TJC-accredited ASCs) at a cost of $4,679,378 ($937 estimated cost for each non TJC-accredited ASC × 4,994 non TJC-accredited ASCs).

TABLE 9—TOTAL COST ESTIMATE FOR A NON-TJC ACCREDITED ASC TO DEVELOP AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$110	4	$440
Registered Nurse-Quality Improvement	71	7	497
Total	....	11	937

All of the ASCs will also be required to review and update their emergency preparedness plans at least annually. For the purpose of determining the burden for this requirement, we will expect that ASCs will review their plans annually. All ASCs have a professional staff person, a quality improvement nurse, whose responsibility entails ensuring that the ASC is delivering quality patient care and that the ASC is complying with regulations concerning patient care. We expect that the quality improvement nurse will be primarily responsible for the annual review of the ASC's emergency preparedness plan. We expect that complying with this requirement will constitute a usual and customary business practice for ASCs in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2). Therefore, we will not include this activity in the burden analysis.

Section 416.54(b) proposed that each ASC be required to develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a), the risk assessment at paragraph (a)(1), and the communication plan set forth in paragraph (c). We will require ASCs to review and update these policies and procedures at least annually. These policies and procedures will be required to include, at a minimum, the requirements listed at § 416.54(b)(1) through (7). We expect that ASCs will develop emergency preparedness policies and procedures based upon their risk assessments, emergency preparedness plans, and communication plans. Therefore, ASCs will need to thoroughly review their emergency preparedness policies and procedures and compare them to all of the information previously noted. The ASCs will then need to revise, or in some cases, develop new policies and procedures that will ensure that the ASCs' emergency preparedness plans address the specific elements.

TJC accreditation standards already require many of the specific elements that are required in this section. For example, in the chapter entitled "Leadership" (LD), TJC-accredited ASCs are required to "develop policies and procedures that guide and support patient care, treatment, and services" (CAMAC, Standard LD.3.90, EP 1, p. LD–12a). In addition, TJC-accredited ASCs must already address or perform a HVA; processes for communicating with and assigning staff under emergency conditions; provision of subsistence or critical needs; evacuation of the facility; and alternate sources for fuel, water, electricity, etc. (CAMAC, Standard EC.4.10, EPs 1, 7–10, 12, and 20, pp. EC–12–13). They must also critique their drills and modify their emergency management plans in response to the critiques (CAMAC, Standard EC.4.20, EPs 12–16, pp. EC–14–14a). In the chapter entitled, "Management of Information" (IM), they are required to protect and preserve the privacy and confidentiality of sensitive data (CAMAC, Standard IM.2.10, EPs 1 and 9, p. IM–6). If TJC-accredited ASCs have any tasks required to satisfy these requirements, we expect they will constitute only a negligible burden. For the 491 TJC-accredited ASCs, the requirement for emergency preparedness policies and procedures will constitute a usual and customary business practice in accordance with the implementing regulations of the PRA 5 CFR 1320.3(b)(2). Therefore, we will not include this activity in the burden analysis for these 491 TJC-accredited ASCs.

AAAHC standards require ASCs to have "the necessary personnel, equipment and procedures to handle medical and other emergencies that may arise in connection with services sought or provided" (AHAHC, Chapter 8. Facilities and Environment, Element B, p. 37). Although, we expect that AAAHC-accredited ASCs probably already have policies and procedures that address at least some of the requirements, we expect that they will sustain a considerable burden in satisfying all of the requirements. We will include the AAAHC-accredited ASCs with the non-accredited ASCs in determining the burden for the requirements in § 416.54(b).

We expect that all of the 4,994 non TJC-accredited ASCs have some emergency preparedness policies and procedures. However, we expect that all of these ASCs will need to review their policies and procedures and revise their policies and procedures to ensure that they address all of the requirements. We expect that the quality improvement nurse will initially review the ASC's emergency preparedness policies and procedures. The quality improvement nurse will send any recommendations for changes or additional policies or procedures to the ASC's administrator. The administrator and quality improvement nurse will need to make the necessary revisions and draft any necessary policies and procedures. We estimate that for each non TJC-accredited ASC to comply with this requirement will require 9 burden hours at a cost of $717. For the 4,994 ASCs to comply with this requirement, it will require an estimated 44,946 burden hours (9 burden hours for each non TJC-accredited ASC × 4,994 non TJC-accredited ASCs) at a cost of $3,580,698. ($717 estimated cost for each non TJC-accredited ASC × 4,994 ASCs).

TABLE 10—TOTAL COST ESTIMATE FOR A NON-TJC ACCREDITED ASC TO DEVELOP NEW POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$110	2	$220
Registered Nurse-Quality Improvement	71	7	497
Total		9	717

Section 416.54(c) will require each ASC to develop and maintain an emergency preparedness communication plan that complies with both federal and state law. We also proposed that ASCs will have to review and update these plans at least annually. These communication plans will have to include the information listed in § 416.54(c)(1) through (7). The burden associated with developing and maintaining an emergency preparedness communication plan will be the time and effort necessary to review, revise, and, if necessary, develop new sections for the ASC's emergency preparedness communications plan to ensure that it satisfied these requirements.

TJC-accredited ASCs are required to have a plan that "identifies backup internal and external communication systems in the event of failure during emergencies" (CAMAC, Standard EC.4.10, EP 18, p. EC–13). There are also requirements for identifying, notifying, and assigning staff, as well as notifying external authorities (CAMAC, Standard EC.4.10, EPs 7–9, p. EC–13). In addition, the facility's plan must provide for controlling information about patients (CAMAC, Standard EC.4.10, EP 10, p. EC–13). If any revisions or additions are necessary to satisfy the requirements, we expect the revisions or additions will be those incurred during the course of normal business and thereby impose no additional burden. Thus, for the TJC-accredited ASCs, the requirements for the emergency preparedness communication plan will constitute a usual and customary business practice for ASCs as stated in the implementing regulations of the PRA at 5 CFR 1320.3(b)(2). Thus, we will not include this activity by these TJC-accredited ASCs in the burden analysis.

The AAAHC standards do not have a specific requirement for a communication plan for emergencies. However, AAAHC-accredited ASCs are required to have the "necessary personnel, equipment and procedures to handle medical and other emergencies that may arise in connection with services sought or provided (AAAHC, 8. Facilities and Environment, Element B, p. 37) and "a comprehensive emergency plan to address internal and external emergencies" (AAAHC, 8. Facilities and Environment, Element D, p. 37). Since AAAHC does have a specific requirement for a communication plan, we will include the AAAHC-accredited ASCs in with the non-accredited ASCs in determining the burden for these requirements for a total of 4,994 non TJC-accredited ASCs (5,485 total ASCs − 491 TJC accredited ASCs).

We expect that all non TJC-accredited ASCs currently have some type of emergency preparedness communication plan. It is standard practice in the healthcare industry to have and maintain contact information for both staff and outside sources of assistance; alternate means of communications in case there is an interruption in phone service to the facility, such as cell phones; and a method for sharing information and medical documentation with other healthcare providers to ensure continuity of care for their patients. We expect that all ASCs already satisfy the requirements in § 416.54(c)(1) through (4). However, for the requirements in § 416.54(c)(5) through (7), all ASCs will need to review, revise, and, if necessary, develop new sections for their plans to ensure that they include all of the requirements. We expect that this will require the involvement of the ASC's administrator and a registered nurse. We estimate that complying with this requirement will require 4 burden hours at a cost of $323. Therefore, for all non

TJC-accredited ASCs to comply with the requirements in this section will require an estimated 19,976 burden hours (4 hours for each non TJC-accredited ASC × 4,994 non TJC-accredited ASCs) at a cost of $1,613,062 ($323 estimated cost for each non TJC-accredited ASC × 4,994 non TJC-accredited ASCs).

TABLE 11—TOTAL COST ESTIMATE FOR A NON-TJC ACCREDITED ASC TO DEVELOP A COMMUNICATION PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$110	1	$110
Registered Nurse-Quality Improvement	71	3	213
Total	....	4	323

We also proposed that ASCs must review and update their emergency preparedness communication plans at least annually. We believe that ASCs already review their emergency preparedness communication plans periodically. Therefore, we believe complying with this requirement will constitute a usual and customary business practice for ASCs as stated in the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 416.54(d) will require ASCs to develop and maintain emergency preparedness training and testing programs that ASCs must review and update at least annually. Specifically, ASCs must meet the requirements listed at § 416.54(d)(1) and (2).

The burden associated with complying with these requirements will be the time and effort necessary for an ASC to review, update, and, in some cases, develop new sections for its emergency preparedness training program. Since ASCs are currently required to conduct drills, at least annually, to test their disaster plan's effectiveness, we expect that all ASCs already provide training on their emergency preparedness policies and procedures. However, all ASCs will need to review their current training and testing programs and compare their contents to their risk assessments, emergency preparedness plans, policies and procedures, and communication plans.

Section 416.54(d)(1) will require ASCs to provide initial training in their emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. ASCs will have to ensure that their staff can demonstrate knowledge of emergency procedures. Thereafter, ASCs will have to provide the training at least annually. TJC-accredited ASCs must provide an initial orientation to their staff and independent practitioners (CAMAC, Standard 2.10, HR–8). They must also provide "on-going education, including in-services, training, and other activities" to maintain and improve staff competence (CAMAC, Standard 2.30, HR–9). We expect that these TJC-accredited ASCs include some training on their facilities' emergency preparedness policies and procedures in their current training programs. However, these requirements do not contain any requirements for training volunteers. Thus, TJC accreditation standards do not ensure that TJC-accredited ASCs are already fulfilling all of the requirements, and we expect that the TJC-accredited ASCs will incur a burden complying with these requirements. Therefore, we will include these TJC-accredited ASCs in determining the burden for these requirements.

The AAAHC-accredited ASCs are already required to ensure that "all health care professionals have the necessary and appropriate training and skills to deliver the services provided by the organization" (AAAHC, Chapter 4. Quality of Care Provided, Element A, p. 28). Since these ASCs are required to have an emergency plan that addresses internal and external emergencies, we expect that all of the AAAHC-accredited ASCs already are providing some training on their emergency preparedness policies and procedures. However, this requirement does not include any requirement for annual training or for any training for staff that are not healthcare professionals. This AAAHC-accredited requirement does not ensure that these ASCs are already complying with the requirements. Therefore, we will include these AAAHC-accredited ASCs in determining the information collection burden for these requirements.

Based upon our experience with ASCs, we expect that all 5,485 ASCs have some type of emergency preparedness training program. We also expect that these ASCs will need to review their training programs and compare them to their risk assessments, emergency preparedness plans, policies and procedures, and communication plans. The ASCs will then need to make any necessary revisions to their training programs to ensure they comply with these requirements. We expect that complying with this requirement will require the involvement of an administrator and a quality improvement nurse. We estimate that for each ASC to develop a comprehensive emergency training program will require 6 burden hours at a cost of $465. Therefore, the estimated annual burden for all 5,485 ASCs to comply with these requirements is 32,910 burden hours (6 burden hours × 5,4855 ASCs) at an estimated cost of $2,550,525 ($465 estimated cost for each ASC × 5,485 ASCs).

TABLE 12—TOTAL COST ESTIMATE FOR AN ASC TO DEVELOP A TRAINING PROGRAM

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$110	1	$110
Registered Nurse-Quality Improvement	71	5	355
Total	....	6	465

We proposed that ASCs will also have to review and update their emergency preparedness training programs at least annually. For the purpose of determining the burden for this requirement, we will expect that ASCs will review their emergency preparedness training program annually. We expect that all ASCs have a quality improvement nurse responsible for ensuring that the ASC is delivering quality patient care and that the ASC is complying with patient care regulations. We expect that a registered nurse will be primarily responsible for the annual review of the ASC's emergency preparedness training program. Thus, in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe complying with this requirement will constitute a usual and customary business practice for ASCs. Thus, we will not include this activity in this burden analysis.

Section 416.54(d)(2) will require ASCs to participate in a full-scale exercise at least annually. ASCs will also have to participate in one additional testing exercise of their choice at least annually. If the ASC experiences an actual natural or man-made emergency that requires activation of their emergency plan, the ASC will be exempt from the requirement for a full-scale exercise for 1 year following the onset of the actual event. ASCs will also be required to analyze their response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise their emergency plans, as needed. To comply with this requirement, ASCs will need to develop a scenario for each drill and exercise. ASCs will also need to develop the documentation necessary for recording what happened during the testing exercises and emergency events and analyze their responses to these events.

TJC-accredited ASCs are required to regularly test their emergency management plans at least twice a year, critique each exercise, and modify their emergency management plans in response to those critiques (CAMAC, Standard EC.4.20, EP 1 and 12–16, p. EC–14–14a). In addition, the scenarios for these drills should be realistic and related to the priority emergencies the ASC identified in its HVA (CAMAC, Standard EC.4.20, EP 5, p. EC–14). However, the EPs for this standard do not contain any requirements for the drills to be community-based; for there to be a paper-based, tabletop exercise; or for the ASCs to maintain documentation of these testing exercises or emergency events. These TJC accreditation requirements do not ensure that TJC-accredited ASCs are already complying with these requirements. Therefore, the TJC-accredited ASCs will be included in the burden estimate.

The AAAHC-accredited ASCs already are required to perform at least four drills annually of their internal emergency plans (AAAHC, Chapter 8. Facilities and Environment, Element E, p. 37). However, there is no requirement for a paper-based, tabletop exercise; for a community-based drill; or for the ASCs to maintain documentation of their testing exercises or emergency events. This AAAHC accreditation requirement does not ensure that AAAHC-accredited ASCs are already complying with these requirements. Therefore, the AAAHC-accredited ASCs will be included in the burden estimate.

Based on our experience with ASCs, we expect that all of the 5,485 ASCs will be required to develop scenarios for their testing exercises and the documentation necessary to record and analyze these events, as well as any emergency events. Although we believe many ASCs may have developed scenarios and documentation for whatever type of drills or exercises they had previously performed, we expect all ASCs will need to ensure that the testing of their emergency preparedness plans comply with these requirements. Based upon our experience with ASCs, we expect that complying with this requirement will require the involvement of an administrator and a registered nurse. We estimate that for each ASC to comply will require 5 burden hours at a cost of $394. Therefore, for all 5,485 ASCs to comply with this requirement will require an estimated 27,425 burden hours (5 burden hours for each ASC × 5,485 ASCs) at a cost of $2,161,090 ($394 estimated cost for each ASC × 5,485 ASCs).

TABLE 13—TOTAL COST ESTIMATE FOR AN ASC TO CONDUCT TRAINING EXERCISES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$110	1	$110
Registered Nurse-Quality Improvement	71	4	284
Total		5	394

TABLE 14—BURDEN HOURS AND COST ESTIMATES FOR ALL 5,485 ASCS TO COMPLY WITH THE ICRS CONTAINED IN § 416.54 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 416.54(a)(1)	0938–New	4,994	4,994	8	39,952	**	3,810,422	3,810,422
§ 416.54(a)(1)–(4)	0938–New	4,994	4,994	11	54,934	**	4,679,378	4,679,378
§ 416.54(b)	0938–New	4,994	4,994	9	44,946	**	3,580,698	3,580,698
§ 416.54(c)	0938–New	4,994	4,994	4	19,976	**	1,613,062	1,613,062
§ 416.54(d)(1)	0938–New	5,485	5,485	6	32,910	**	2,550,525	2,550,525
§ 416.54(d)(2)	0938–New	5,485	5,485	5	27,425	**	2,161,090	2,161,090
Totals		10,479	30,946		220,143			18,395,175.00

** The hourly labor cost is blended between the wages for multiple staffing levels.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 14.

E. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 418.113)

Section 418.113(a) will require hospices to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. We proposed that the plan meet the criteria listed in § 418.113(a)(1) through (4).

Although § 418.113(a) is entitled "Emergency Plan" and the requirement for the plan is stated first, the emergency plan must include and be based upon a risk assessment. Therefore, since hospices must perform their risk assessments before beginning, or at least before they complete, their plans, we will discuss the burden related to performing the risk assessment first.

Section 418.113(a)(1) will require all hospices to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. We expect that in performing a risk assessment, a hospice will need to consider its physical location, the geographic area in which it is located, and its patient population.

The burden associated with this requirement will be the time and effort necessary to perform a thorough risk assessment. There are 4,401 hospices. There are 3,989 hospices that provide care only to patients in their homes (home health based and freestanding hospices) and 412 hospices that offer inpatient care directly (hospital, SNF, and NF based hospices). When we use the term "inpatient hospice," we are referring to a hospice that operates its own inpatient care facility; that is, the hospice provides the inpatient care itself. By "outpatient hospices", we are referring to hospices that only provide in-home care, and contract with other facilities to provide inpatient care. The current requirements for hospices contain emergency preparedness requirements for inpatient hospices only (§ 418.110). Inpatient hospices must have "a written disaster preparedness plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that will affect the hospice's ability to provide care," as stated in § 418.110(c)(1)(ii). Thus, we expect inpatient hospices already have performed some type of risk assessment during the process of developing their disaster preparedness plan. However, these risk assessments may not be documented or may not address all of the requirements under § 418.113(a). Therefore, we believe that all inpatient hospices will have to conduct a thorough review of their current risk assessments and then perform the necessary tasks to ensure that their facilities' risk assessments comply with these requirements.

We have not designated any specific process or format for hospices to use in conducting their risk assessments because we believe hospices need maximum flexibility in determining the best way for their facilities to accomplish this task. However, we believe that in the process of developing a risk assessment, healthcare institutions should include representatives from or obtain input from all of their major departments. Based on our experience with hospices, we expect that conducting the risk assessment will require the involvement of the hospice's administrator and an interdisciplinary group (IDG). The current Hospice CoPs require every hospice to have an IDG that includes a physician, registered nurse, social worker, and pastoral or other counselor. The responsibilities of one of a hospice's IDGs, if they have more than one, include the establishment of "policies governing the day-to-day provision of hospice care and services" (§ 418.56(a)(2)). Thus, we believe the IDG will be involved in performing the risk assessment.

We expect that members of the IDG will attend an initial meeting; review any existing risk assessment; develop comments and recommendations for changes to the assessment; attend a follow-up meeting; perform a final review; and approve the risk assessment. We expect that the administrator will coordinate the meetings, perform an initial review of the current risk assessment, provide a critique of the risk assessment, offer suggested revisions, coordinate comments, develop the new risk assessment, and ensure that the necessary staff approves the new risk assessment. We believe it is likely that the administrator will spend more time reviewing and working on the risk assessment than the other individuals in the IDG. We estimate it will require 10 burden hours to review and update the risk assessment at a cost of $759. There are 412 inpatient hospices. Therefore, based on that estimates, it will require 4,120 burden hours (10 burden hours for each inpatient hospice × 412 inpatient hospices) for all inpatient hospices to comply with this requirement at a cost of $312,708 ($759 estimated cost for each inpatient hospice × 412 inpatient hospices).

TABLE 15—TOTAL COST ESTIMATE FOR AN INPATIENT HOSPICE TO CONDUCT A RISK ASSESSMENT

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$80	4	$320
Physician	180	1	180
Counselor	34	1	34
Social Worker	45	1	45
Registered Nurse	60	3	180
Totals		10	759

There are no emergency preparedness requirements in the current hospice CoPs for hospices that provide care to patients in their homes. However, it is standard practice for healthcare facilities to plan and prepare for common emergencies, such as fires, power outages, and storms. Although we expect that these hospices have considered at least some of the risks they might experience, we anticipate that these facilities will require more time than an inpatient hospice to perform a risk assessment. We estimate that each hospice that provides care to patients in their homes will require 12 burden hours to develop its risk assessment at a cost of $899. Therefore, based on that estimate, for all 3,989 hospices that provide care to patients in their homes, it will require 47,868 burden hours (12 burden hours for each hospice × 3,989 hospices) to comply with this requirement at a cost of $3,586,111 ($899 estimated cost for each hospice × 3,989 hospices). Based on the previous calculations, we estimate that for all 4,401 hospices to develop a risk assessment will require 51,988 burden hours at a cost of $3,898,819.

TABLE 16—TOTAL COST ESTIMATE FOR AN OUTPATIENT HOSPICE TO CONDUCT A RISK ASSESSMENT

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$80	5	$400
Physician	180	1	180
Counselor	34	1	34
Social Worker	45	1	45
Registered Nurse	60	4	240
Totals	....	12	899

After conducting the risk assessments, hospices will have to develop and maintain emergency preparedness plans that they will have to review and update at least annually. We expect all hospices to compare their current emergency plans, if they have them, to the risk assessments they performed in accordance with § 418.113(a)(1). In addition, hospices will have to comply with the requirements in § 418.113(a)(1) through (4). They will then need to review, revise, and, if necessary, develop new sections of their plans to ensure they comply with these requirements.

The current hospice CoPs require inpatient hospices to have "a written disaster preparedness plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that will affect the hospice's ability to provide care" (§ 418.110(c)(1)(ii)). We believe that all inpatient hospices already have some type of emergency preparedness or disaster plan. However, their plans may not address all likely medical and non-medical emergency events identified by the risk assessment. Furthermore, their plans may not include strategies for addressing likely emergency events or address their patient population; the type of services they have the ability to provide in an emergency; or continuity of operations, including delegations of authority and succession plans. We expect that an inpatient hospice will have to review its current plan and compare it to its risk assessment, as well as to the other requirements we proposed. We expect that most inpatient hospices will need to update and revise their existing emergency plans, and, in some cases, develop new sections to comply with our requirements.

The burden associated with this requirement will be the time and effort necessary to develop an emergency preparedness plan or to review, revise, and develop new sections for an existing emergency plan. Based upon our experience with inpatient hospices, we expect that these activities will require the involvement of the hospice's administrator and an IDG, that is, a physician, registered nurse, social worker, and counselor. We believe that developing the plan will require more time to complete than the risk assessment.

We expect that these individuals will have to attend an initial meeting, review relevant sections of the facility's current emergency preparedness or disaster plan(s), develop comments and recommendations for changes to the facility's plan, attend a follow-up meeting, perform a final review, and approve the emergency plan. We expect that the administrator will probably coordinate the meetings, perform an initial review of the current emergency plan, provide a critique of the emergency plan, offer suggested revisions, coordinate comments, develop the new emergency plan, and ensure that the necessary parties approve the new emergency plan. We expect the administrator will probably spend more time reviewing and working on the emergency plan than the other individuals. We estimate that it will require 14 burden hours for each inpatient hospice to develop its emergency preparedness plan at a cost of $1,159. Based on this estimate, it will require 5,768 burden hours (14 burden hours for each inpatient hospice × 412 inpatient hospices) for all inpatient hospices to complete their plans at a cost of $477,508 ($1,159 estimated cost for each inpatient hospice × 412 inpatient hospices).

TABLE 17—TOTAL COST ESTIMATE FOR AN INPATIENT HOSPICE TO DEVELOP AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$80	6	$480
Physician	180	2	360
Counselor	34	1	34
Social Worker	45	1	45
Registered Nurse	60	4	240
Totals	....	14	1,159

As discussed earlier, we have no current regulatory requirement for hospices that provide care to patients in their homes to have emergency preparedness plans. However, it is standard practice for healthcare providers to plan for common emergencies, such as fires, power outages, and storms. Although we expect that these hospices already have some type of emergency or disaster plan, each hospice will need to review its emergency plan to ensure that it addressed the risks identified in its risk assessment and complied with the requirements. We expect that an administrator and the individuals from the hospice's IDG will be involved in reviewing, revising, and developing a facility's emergency plan. However, since there are no current requirements for hospices that provide care to patients in their homes have emergency plans, we believe it will require more time for each of these hospices than for inpatient hospices to complete an emergency plan. We estimate that for each hospice that provides care to patients in their homes to comply with this requirement will require 20 burden hours at an estimated cost of $1,599. Based on that estimate, for all 3,989 of these hospices to comply with this requirement will require 79,780 burden hours (20 burden hours for each hospice × 3,989 hospices) at a cost of $6,378,411 ($1,599 estimated cost for each hospice × 3,989 hospices). We estimate that for all 4,401 hospices to develop an emergency preparedness plan will require 6,378,411 burden hours at a cost of $6,855,919.

TABLE 18—TOTAL COST ESTIMATE FOR AN OUTPATIENT HOSPICE TO DEVELOP AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$80	10	$800
Physician	180	2	360
Counselor	34	1	34
Social Worker	45	1	45
Registered Nurse	60	6	360
Totals	....	20	1,599

Hospices will also be required to review and update their emergency preparedness plans at least annually. The current hospice CoPs require inpatient hospices to periodically review and rehearse their disaster preparedness plan with their staff, including non-employee staff (42 CFR 418.110(c)(1)(ii)). For purposes of this burden estimate, we will expect that under this final rule, inpatient hospices will review their emergency plans prior to reviewing them with all of their employees and that this review will occur annually.

Outpatient hospices, either home based or freestanding, on the other hand, currently do not have emergency preparedness requirements in the current hospice CoPs and as such, there is no requirement for an annual review of the plan. Therefore, we will analyze the burden from this requirement for outpatient hospices.

Based on our experience with outpatient hospices, we expect that the same individuals who develop the emergency preparedness plan will annually review and update the plan. These staff would include the administrator, physician, counselor, social worker, and registered nurse. We estimate that for each hospice that provides care to patients in an outpatient setting to comply with this requirement will require 8 burden hours at an estimated cost of $619. Based on that estimate, for all 3,989 of these hospices to comply with this requirement will require 31,912 burden hours (8 burden hours for each hospice × 3,989 hospices) at a cost of $2,469,191 ($619 estimated cost for each hospice × 3,989 hospices).

TABLE 19—TOTAL COST ESTIMATE FOR AN OUTPATIENT HOSPICE TO REVIEW AND UPDATE AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$80	3	$240
Physician	180	1	180
Counselor	34	1	34
Social Worker	45	1	45
Registered Nurse	60	2	120
Totals	....	8	619

We expect that all hospices, both inpatient and those that provide care to patients in their homes, have an administrator who is responsible for the day-to-day operation of the hospice. Day-to-day operations will include ensuring that all of the hospice's plans are up-to-date and in compliance with relevant federal, state, and local laws, regulations, and ordinances. In addition, it is standard practice in healthcare organizations to have a professional employee, an administrator, who periodically reviews their plans and procedures. We expect that complying with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2). Thus, we will not include this activity in the burden analysis.

Section 418.113(b) will require each hospice to develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a), the risk assessment at paragraph (a)(1), and the communication plan at paragraph (c). It will also require hospices to review and update these policies and procedures at least annually. At a minimum, the hospice's policies and procedures will be required to address the requirements listed at § 418.113(b)(1) through (6).

We expect that all hospices have some emergency preparedness policies and procedures because the current hospice CoPs for inpatient hospices already require them to have "a written disaster preparedness plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that will affect the hospice's ability to provide care" (§ 418.110(c)(1)(ii)). In addition, the responsibilities for at least one of a hospice's IDGs, if they have more than one, include the establishment of "policies governing the day-to-day provision of hospice care and services" (§ 418.56(a)(2)). However, we also expect that all inpatient hospices will need to review their current policies and procedures, assess whether they contain everything required by their facilities' emergency preparedness plans, and revise and update them as necessary.

The burden associated with reviewing, revising, and updating a hospice's emergency policies and procedures will be the resources needed to ensure they comply with these requirements. Since at least one of a hospice's IDGs will be responsible for developing policies that govern the daily care and services for hospice patients (42 CFR 418.56(a)(2)), we expect that an IDG will be involved with reviewing and revising a hospice's existing policies and procedures and developing any necessary new policies and procedures. We estimate that an inpatient hospice's compliance with this requirement will require 8 burden hours at a cost of $619. Therefore, based on that estimate, all 412 inpatient hospices' compliance with this requirement will require 3,296 burden hours (8 burden hours for each inpatient hospice × 412 inpatient hospices) at a cost of $255,028 ($619 estimated cost for each inpatient hospice × 412 inpatient hospices).

TABLE 20—TOTAL COST ESTIMATE FOR AN INPATIENT HOSPICE TO DEVELOP NEW POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$80	3	$240
Physician	180	1	180
Counselor	34	1	34
Social Worker	45	1	45
Registered Nurse	60	2	120
Totals	....	8	619

Although there are no existing regulatory requirements for hospices that provide care to patients in their homes to have emergency preparedness policies and procedures, it is standard practice for healthcare organizations to prepare for common emergencies, such as fires, power outages, and storms. We expect that these hospices already have some emergency preparedness policies and procedures. However, under this final rule, the IDG for these hospices will need to accomplish the same tasks as described earlier for inpatient hospices to ensure that these policies and procedures comply with the requirements.

We estimate that each hospice's compliance with this requirement will require 9 burden hours at a cost of $699. Therefore, based on that estimate, all 3,989 hospices that provide care to patients in their homes to comply with this requirement will require 35,901 burden hours (9 burden hours for each hospice × 3,989 hospices) at a cost of $2,788,311 ($699 estimated cost for each hospice × 3,989 hospices).

Thus, we estimate that development of emergency preparedness policies and procedures for all 4,401 hospices will require 39,197 burden hours at a cost of $3,043,339.

TABLE 21—TOTAL COST ESTIMATE FOR AN OUTPATIENT HOSPICE TO DEVELOP NEW POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$80	4	$320
Physician	180	1	180
Counselor	34	1	34
Social Worker	45	1	45
Registered Nurse	60	2	120
Totals	....	9	699

Section 418.113(c) will require a hospice to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. Hospices will also have to review and update their plans at least annually. The communication plan will have to include the requirements listed at § 418.113(c)(1) through (7).

We believe that all hospices already have some type of emergency preparedness communication plan. Although only inpatient hospices have a current requirement for disaster preparedness (§ 418.110(c)), it is standard practice for healthcare organizations to maintain contact information for their staff and for outside sources of assistance; alternate means of communications in case there is an interruption in phone service to the organization (for example, cell phones); and a method for sharing information and medical documentation with other healthcare providers to ensure continuity of care for their patients. However, many hospices, both inpatient hospices and hospices that provide care to patients in their homes, may not have formal, written emergency preparedness communication plans. We expect that all hospices will need to review, update, and in some cases, develop new sections for their plans to ensure that those plans include all of the elements we proposed requiring for hospice communication plans.

The burden associated with complying with this requirement will be the resources required to ensure that the hospice's emergency communication plan complied with these requirements. Based upon our experience with hospices, we anticipate that satisfying these requirements will require only the involvement of the hospice's administrator. Thus, for each hospice, we estimate that complying with this requirement will require 3 burden hours at a cost of $240. Therefore, based on that estimate, compliance with this requirement for all 4,401 hospices will require 13,203 burden hours (3 burden hours for each hospice × 4,401 hospices) at a cost of $1,056,240 ($240 estimated cost for each hospice × 4,401 hospices).

TABLE 22—TOTAL COST ESTIMATE FOR A HOSPICE TO DEVELOP A COMMUNICATION PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$80	3	$240
Totals		3	240

Section 418.113(d) will require each hospice to develop and maintain an emergency preparedness training and testing program that will be reviewed and updated at least annually. Section 418.113(d)(1) will require hospices to provide initial training in emergency preparedness policies and procedures to all hospice employees, consistent with their expected roles, and maintain documentation of the training. The hospice will also have to ensure that their employees could demonstrate knowledge of their emergency procedures. Thereafter, the hospice will have to provide emergency preparedness training at least annually. Hospices will also be required to periodically review and rehearse their emergency preparedness plans with their employees, with special emphasis placed on carrying out the procedures necessary to protect patients and others.

Under current regulations, all hospices are required to provide an initial orientation and in-service training and educational programs, as necessary, to each employee (§ 418.100(g)(2) and (3)). They must also provide employee orientation and training consistent with hospice industry standards (§ 418.78(a)). In addition, inpatient hospices must periodically review and rehearse their disaster preparedness plans with their staff, including non-employee staff (§ 418.110(c)(1)(ii)). We expect that all hospices already provide training to their employees on the facility's existing disaster plans, policies, and procedures. However, under this final rule, all hospices will need to review their current training programs and compare their contents to their updated emergency preparedness plans, policies and procedures, and communications plans. Hospices will then need to review, revise, and in some cases, develop new material for their training programs so that they complied with these requirements.

The burden associated with the previously discussed requirements will be the time and effort necessary for a hospice to bring itself into compliance with the requirements in this section. We expect that compliance with this requirement will require the involvement of a registered nurse. We expect that the registered nurse will compare the hospice's current training program with the facility's emergency preparedness plan, policies and procedures, and communication plan, and then make any necessary revisions, including the development of new training material, as needed. We estimate that these tasks will require 6 burden hours at a cost of $360. Based on this estimate, compliance by all 4,401 hospices will require 26,406 burden hours (6 burden hours for each hospice × 4,401 hospices) at a cost of $1,584,360 ($360 estimated cost for each hospice × 4,401 hospices). We are proposing that hospices also be required to review and update their emergency preparedness training programs at least annually.

TABLE 23—TOTAL COST ESTIMATE FOR A HOSPICE TO DEVELOP A TRAINING PROGRAM

Position	Hourly wage	Burden hours	Cost estimate
Registered Nurse	$60	6	$360
Totals		6	360

Section 418.113(d)(2) will require hospices to participate in a full-scale exercise at least annually. Hospices are also required to participate in one additional testing exercise of their choice at least annually. Hospices will also be required to analyze their responses to and maintain documentation of all their drills, tabletop exercises, and emergency events, and revise their emergency plans, as needed. To comply with this requirement, a hospice will need to develop scenarios for their drills and exercises. A hospice also will have to develop the required documentation.

Hospices will also have to periodically review and rehearse their emergency preparedness plans with their staff (including nonemployee staff), with special emphasis on carrying out the procedures necessary to protect patients and others (§ 418.110(c)(1)(ii)). However, this periodic rehearsal requirement does not ensure that hospices are performing any type of drill or exercise annually or that they are documenting their responses. In addition, there is no requirement in the current CoPs for outpatient hospices to have an emergency plan or for these hospices to test any emergency procedures they may currently have. We believe that developing the scenarios for these drills and exercises and the documentation necessary to record the events during testing exercises and emergency events will be new requirements for all hospices.

The associated burden will be the time and effort necessary for a hospice to comply with these requirements. We expect that complying with these requirements will require the involvement of a registered nurse. We expect that the registered nurse will develop the necessary documentation and the scenarios for the drills and exercises. We estimate that these tasks will require 4 burden hours at an estimated cost of $240. Based on this estimate, in order for all 4,401 hospices to comply with these requirements, it will require 17,604 burden hours (4 burden hours for each hospice × 4,401 hospices) at a cost of $1,056,240 ($240 estimated cost for each hospice × 4,401 hospices).

Thus, for all 4,401 hospices to comply with all of the requirements in § 418.113, it will require an estimated 265,858 burden hours at a cost of $19,964,108.

Comment: A commenter expressed that we underestimated the burden and additional cost for hospices to comply with these requirements since hospice providers will be fairly new to many of these standards. The commenter indicated that hospices have not typically been participants in local, state, or federal emergency preparedness and response plans, so they will have to work even harder than other providers to build connections. The commenter suggested that CMS re-evaluate the burden estimates in the COI section for hospices.

Response: We agree that hospices may not be typically involved in local, state, or federal emergency planning, however, as we stated, it is standard practice for healthcare providers to plan for common emergencies, such as fires, power outages, and storms. We expect that hospices already have some type of emergency or disaster plan, therefore we assigned burden based on the principle that each hospice will need to review its current emergency plan to ensure that it addressed the risks identified in its risk assessment and complies with the requirements. We also expect that all hospices have some emergency preparedness policies and procedures because the current hospice CoPs for inpatient hospices already require them to have "a written disaster preparedness plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that will affect the hospice's ability to provide care" (42 CFR 418.110(c)(1)(ii)). Given these current CoPs, we believe that the burden estimates for hospices are appropriate.

TABLE 24—TOTAL COST ESTIMATE FOR A HOSPICE TO CONDUCT TESTING EXERCISES

Position	Hourly wage	Burden hours	Cost estimate
Registered Nurse	$60	4	$240
Totals	....	4	240

TABLE 25—BURDEN HOURS AND COST ESTIMATES FOR ALL 4,401 HOSPICES TO COMPLY WITH THE ICRS IN § 418.113 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 418.113(a) (outpatient)	0938–New	3,989	3,989	8	31,912	**	2,469,191	2,469,191
§ 418.113(a)(1) (inpatient)	0938–New	412	412	10	4,120	**	312,708	312,708
§ 418.113(a)(1) (outpatient)	0938–New	3,989	3,989	12	47,868	**	3,586,111	3,586,111
§ 418.113(a)(1)–(4) (inpatient)	0938–New	412	412	14	5,768	**	477,508	477,508
§ 418.113(a)(1)–(4) (outpatient)	0938–New	3,989	3,989	20	79,780	**	6,378,411	6,378,411
§ 418.113(b) (inpatient)	0938–New	412	412	8	3,296	**	255,028	255,028
§ 418.113(b) (outpatient)	0938–New	3,989	3,989	9	35,901	**	2,788,311	2,788,311
§ 418.113(c)	0938–New	4,401	4,401	3	13,203	**	1,056,240	1,056,240
§ 418.113(d)(1)	0938–New	4,401	4,401	6	26,406	**	1,584,360	1,584,360
§ 418.113(d)(2)	0938–New	4,401	4,401	4	17,604	**	1,056,240	1,056,240
Totals	....	8,802	30,395	....	265,858	....	....	19,964,108

** The hourly labor cost is blended between the wages for multiple staffing levels.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 25.

F. ICRs Regarding Emergency Preparedness (§ 441.184)

Section 441.184(a) will require Psychiatric Residential Treatment Facilities (PRTFs) to develop and maintain emergency preparedness plans and review and update those plans at least annually. We proposed that these plans meet the requirements listed at § 441.184(a)(1) through (4).

Section § 441.184(a)(1) will require each PRTF to develop a documented, facility-based and community-based risk assessment that will utilize an all-hazards approach. We expect that all PRTFs have already performed some of the work needed for a risk assessment because it is standard practice for healthcare facilities to prepare for common hazards, such as fires and power outages, and disasters or emergencies common in their geographic area, such as snowstorms or hurricanes. However, many PRTFs may not have documented their risk assessments or performed one that will comply with all of our requirements. Therefore, we expect that all PRTFs will have to review and revise their current risk assessments.

We do not designate any specific process or format for PRTFs to use in conducting their risk assessments because we believe that PRTFs need maximum flexibility to determine the best way to accomplish this task. However, we expect that PRTFs will include representation from or seek input from all of their major departments. Based on our experience with PRTFs, we expect that conducting the risk assessment will require the involvement of the PRTF's administrator, a psychiatric registered nurse, and a clinical social worker. We expect that all of these individuals will attend an initial meeting, review their current assessment, develop comments and recommendations for changes, attend a follow-up meeting, perform a final review, and approve the new risk assessment. We expect that the psychiatric registered nurse will coordinate the meetings, perform an initial review, offer suggested revisions, coordinate comments, develop a new risk assessment, and ensure that the necessary parties approve the new risk assessment. We also expect that the psychiatric registered nurse will spend more time reviewing and working on the risk assessment than the other individuals. We estimate that in order for each PRTF to comply, it will require 8 burden hours at a cost of $544. There are currently 377 PRTFs. Therefore, based on that estimate, compliance by all PRTFs will require 3,016 burden hours (8 burden hours for each PRTF × 377 PRTFs) at a cost of $205,088 ($544 estimated cost for each PRTF × 377 PRTFs).

TABLE 26—TOTAL COST ESTIMATE FOR A PRTF TO CONDUCT A RISK ASSESSMENT

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$93	2	$186
Social Worker	51	2	102
Registered Nurse	64	4	256
Total	....	8	544

After conducting the risk assessment, § 441.184(a)(1) through (4) will require PRTFs to develop and maintain an emergency preparedness plan. Although it is standard practice for healthcare facilities to have some type of emergency preparedness plan, all PRTFs will need to review their current plans and compare them to their risk assessments. Each PRTF will need to update, revise, and, in some cases, develop new sections to complete its emergency preparedness plan.

Based upon our experience with PRTFs, we expect that the administrator and psychiatric registered nurse who were involved in developing the risk assessment will be involved in developing the emergency preparedness plan. However, we expect it will require substantially more time to complete the plan than the risk assessment. We expect that the psychiatric nurse will be the most heavily involved in reviewing and developing the PRTF's emergency preparedness plan. We also expect that a clinical social worker will review the drafts of the plan and provide comments on it to the psychiatric registered nurse. We estimate that for each PRTF to comply with this requirement will require 12 burden hours at a cost of $858. Thus, we estimate that it will require 4,524 burden hours (12 burden hours for each PRTF × 377 PRTFs) for all PRTFs to comply with this requirement at a cost of $323,466 ($858 estimated cost per PRTF × 377 PRTFs).

TABLE 27—TOTAL COST ESTIMATE FOR A PRTF TO DEVELOP AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$93	4	$372
Social Worker	51	2	102
Registered Nurse	64	6	384
Total	....	12	858

The PRTFs also will be required to review and update their emergency preparedness plans at least annually. However, under the current CoPs, PRTFs are not required to develop an emergency preparedness plan and as such, there is no requirement for an annual review of the plan. Therefore, we will analyze the burden from this requirement for all PRTFs.

Based on our experience with PRTFs, we estimate that an additional burden will be associated with reviewing the plan at least annually and we anticipate that the same staff that will be involved with developing the emergency preparedness plan will also be involved in the annual review and update of the plan. The staff would include the administrator, clinical social worker, and psychiatric registered nurse. We estimate that for each PRTF to comply with this requirement will require 4 burden hours at an estimated cost of $272. Thus, we estimate that it will require 1,508 burden hours (4 burden hours for each PRTF × 377 PRTFs) for all PRTFs to comply with this requirement at a cost of $130,288 ($272 estimated cost per PRTF × 377 PRTFs).

TABLE 28—TOTAL COST ESTIMATE FOR A PRTF TO REVIEW AND UPDATE AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$93	1	$93
Social Worker	51	1	51
Registered Nurse	64	2	128
Total	....	4	272

Section 441.184(b) will require each PRTF to develop and implement emergency preparedness policies and procedures, based on their emergency plan set forth in paragraph (a), the risk assessment at paragraph (a)(1), and the communication plan at paragraph (c). We also proposed requiring PRTFs to review and update these policies and procedures at least annually. At a minimum, we will require that the PRTF's policies and procedures address the requirements listed at § 441.184(b)(1) through (8).

Since we expect that all PRTFs already have some type of emergency plan, we also expect that all PRTFs have some emergency preparedness policies and procedures. However, we expect that all PRTFs will need to review their policies and procedures; compare them to their risk assessments, emergency preparedness plans, and communication plans they developed in accordance with § 441.183(a)(1), (a) and (c), respectively; and then revise their policies and procedures accordingly.

We expect that the administrator and a psychiatric registered nurse will be involved in reviewing and revising the policies and procedures and, if needed, developing new policies and procedures. We estimate that it will require 9 burden hours at a cost of $663 for each PRTF to comply with this requirement. Based on this estimate, it will require 3,393 burden hours (9 burden hours for each PRTF × 377 PRTFs) for all PRTFs to comply with this requirement at a cost of $249,951 ($6632 estimated cost per PRTF × 377 PRTFs).

TABLE 29—TOTAL COST ESTIMATE FOR A PRTF TO DEVELOP POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$93	3	$279
Registered Nurse	64	6	384
Total		9	663

Section 441.184(c) will require each PRTF to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. PRTFs also will have to review and update these plans at least annually. The communication plan will have to include the information set out in § 441.184(c)(1) through (7).

We expect that all PRTFs have some type of emergency preparedness communication plan. It is standard practice for healthcare facilities to maintain contact information for both staff and outside sources of assistance; alternate means of communication in case there is an interruption in phone service to the facility; and a method for sharing information and medical documentation with other healthcare providers to ensure continuity of care for their residents. However, most PRTFs may not have formal, written emergency preparedness communication plans. Therefore, we expect that all PRTFs will need to review and, if needed, revise their plans.

Based on our experience with PRTFs, we anticipate that satisfying these requirements will require the involvement of the PRTF's administrator and a psychiatric registered nurse to review, revise, and if needed, develop new sections for the PRTF's emergency preparedness communication plan. We estimate that for each PRTF to comply will require 5 burden hours at a cost of $378. Based on that estimate, for all PRTFs to comply will require 1,885 burden hours (5 burden hours for each PRTF × 377 PRTFs) at a cost of $142,506 ($378 estimated cost for each PRTF × 377 PRTFs).

TABLE 30—TOTAL COST ESTIMATE FOR A PRTF TO DEVELOP A COMMUNICATION PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$93	2	$186
Registered Nurse	64	3	192
Total		5	378

Section 441.184(d) will require PRTFs to develop and maintain emergency preparedness training programs and review and update those programs at least annually. Section 441.184(d)(1) will require PRTFs to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. The PRTF will also have to ensure that their staff could demonstrate knowledge of the emergency procedures. Thereafter, the PRTF will have to provide emergency preparedness training at least annually.

Based on our experience with PRTFs, we expect that all PRTFs have some type of emergency preparedness training program. However, PRTFs will need to review their current training programs and compare them to their risk assessments and emergency preparedness plans, policies and procedures, and communication plans and update and, in some cases, develop new sections for their training programs.

We expect that complying with this requirement will require the involvement of a psychiatric registered nurse. We expect that the psychiatric registered nurse will review the PRTF's current training program; determine what tasks will need to be performed and what materials will need to be developed; and develop the necessary materials. We estimate that for each PRTF to comply with the requirements in this section will require 10 burden hours at a cost of $640. Based on this estimate, for all PRTFs to comply with this requirement will require 3,770 burden hours (10 burden hours for each PRTF × 377 PRTFs) at a cost of $241,280 ($640 estimated cost for each PRTF × 377 PRTFs).

TABLE 31—TOTAL COST ESTIMATE FOR A PRTF TO DEVELOP A TRAINING PROGRAM

Position	Hourly wage	Burden hours	Cost estimate
Registered Nurse	$64	10	$640
Total		10	640

Section 441.184(d)(2) will require PRTFs to participate in a full-scale exercise at least annually. PRTFs are also required to participate in one additional testing exercise of their choice at least annually. PRTFs will also have to analyze their responses to and maintain documentation of all drills, tabletop exercises, and emergency

events, and revise their emergency plans, as needed. However, if a PRTF experienced an actual natural or man-made emergency that required activation of its emergency plan, that PRTF will be exempt from engaging in a community or a full-scale exercise for 1 year following the onset of the actual emergency event. To comply with this requirement, PRTFs will need to develop scenarios for each drill and exercise and the documentation necessary to record and analyze testing exercises and actual emergency events.

Based on our experience with PRTFs, we expect that all PRTFs have some type of emergency preparedness testing program and most, if not all, PRTFs already conduct some type of drill or exercise to test their emergency preparedness plans. We also expect that they have already developed some type of documentation for testing exercises and emergency events. However, we do not expect that all PRTFs are conducting two testing exercises annually or have developed the appropriate documentation. Thus, we will analyze the burden of these requirements for all PRTFs.

Based on our experience with PRTFs, we expect that the same individual who developed the emergency preparedness training program will develop the scenarios for the testing exercises and the accompanying documentation. We estimate that for each PRTF to comply with the requirements in this section will require 3 burden hours at a cost of $192. We estimate that for all PRTFs to comply will require 1,131 burden hours (3 burden hours for each PRTF × 377 PRTFs) at a cost of $72,384 ($192 estimated cost for each PRTF × 377 PRTFs).

TABLE 32—TOTAL COST ESTIMATE FOR A PRTF TO CONDUCT TESTING EXERCISES

Position	Hourly wage	Burden hours	Cost estimate
Registered Nurse	$64	3	$192
Total		3	192

Based on the previous analysis, for all 377 PRTFs to comply with the ICRs in this final rule will require 17,719 burden hours at a cost of $1,234,675.

TABLE 33—BURDEN HOURS AND COST ESTIMATES FOR ALL 377 PRTFS TO COMPLY WITH THE ICRS CONTAINED IN § 441.184 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 441.184(a)	0938-New	377	377	4	1,508	**	130,288	130,288
§ 441.184(a)(1)	0938-New	377	377	8	3,016	**	205,088	205,088
§ 441.184(a)(1)-(4)	0938-New	377	377	12	4,524	**	323,466	323,466
§ 441.184(b)	0938-New	377	377	9	3,393	**	249,951	249,951
§ 441.184(c)	0938-New	377	377	5	1,885	**	142,506	142,506
§ 441.184(d)(1)	0938-New	377	377	10	3,770	**	241,280	241,280
§ 441.184(d)(2)	0938-New	377	377	3	1,131	**	72,384	72,384
Totals		377	2,639		19,277			1,364,963

** The hourly labor cost is blended between the wages for multiple staffing levels.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 33.

G. ICRs Regarding Emergency Preparedness (§ 460.84)

Section 460.84(a) will require the Program for the All-Inclusive Care for the Elderly (PACE) organizations to develop and maintain emergency preparedness plans and review and update those plans at least annually. We proposed that each plan must meet the requirements listed at § 460.84(a)(1) through (4).

Section 460.84(a)(1) will require PACE organizations to develop documented, facility-based and community-based risk assessments utilizing an all-hazards approach. We believe that the performance of a risk assessment is a standard practice, and that all of the PACE organizations have already conducted some sort of risk assessment based on common emergencies the organization might encounter, such as fires, loss of power, loss of communications, etc. Therefore, we believe that each PACE organization should have already performed some sort of risk assessment.

Under the current regulations, PACE organizations are required to establish, implement, and maintain procedures for managing medical and non-medical emergencies and disasters that are likely to threaten the health or safety of the participants, staff, or the public (§ 460.72(c)(1)). The definition of "emergencies" includes natural disasters that are likely to occur in the PACE organization's area (§ 460.72(c)(2)). PACE organizations are required to plan for emergencies involving participants who are in their center(s) at the time of an emergency, as well as participants receiving services in their homes.

For the purpose of determining the burden, we will assume that a PACE organization's risk assessment, emergency plan, policies and procedures, communication plan, and training and testing program will apply to all of a PACE organization's centers. Based on the existing PACE regulations, we expect that they already assess their physical structure(s), the areas in which they are located, and the location(s) of their participants. However, these risk assessments may not be documented or address all of our requirements. Therefore, we expect that all 119 PACE organizations will have to review, revise, and update their current risk assessments.

We have not designated any specific process or format for PACE organizations to use in conducting their risk assessments because we believe that they will be able to determine the best way for their facilities to accomplish this task. However, we expect that they will include representation or input from all of their major departments. Based on our experience with PACE organizations, we expect that conducting the risk assessment will require the involvement of the PACE organization's program director, medical director, home care coordinator, quality improvement nurse, social worker, and a driver. We expect that these individuals will either attend an initial meeting or individually review relevant sections of the current risk assessment and prepare and forward their comments to the quality assurance nurse. After initial comments are received, some will attend a follow-up meeting, perform a final review, and ensure the new risk assessment was approved by the appropriate individuals. We expect that the quality improvement nurse will coordinate the meetings, review the current risk assessment, suggest revisions, coordinate comments, develop the new risk assessment, and ensure that the necessary parties approve it. We expect that the quality improvement nurse and the home care coordinator will spend more time reviewing and developing the risk assessment than the other individuals. We estimate that complying with the requirement to conduct a risk assessment will require 14 burden hours at a cost of $1,105. For all 119 PACE organizations to comply with this requirement will require an estimated 1,666 burden hours (14 burden hours for each PACE organization × 119 PACE organizations) at a cost of $131,495 ($1,105 estimated cost for each PACE organization × 119 PACE organizations).

TABLE 34—TOTAL COST ESTIMATE FOR A PACE TO CONDUCT A RISK ASSESSMENT

Position	Hourly wage	Burden hours	Cost estimate
Program Director	$110	3	$330
Medical Director	182	1	182
Home Care Coordinator	64	4	256
Registered Nurse/Quality Improvement	64	4	256
Social Worker	55	1	55
Driver	26	1	26
Total	....	14	1,105

After conducting a risk assessment, PACE organizations will have to develop and maintain emergency preparedness plans that satisfied all of the requirements in § 460.84(a)(1) through (4). In addition to the requirement to establish, implement, and maintain procedures for managing emergencies and disasters, current regulations require PACE organizations to have a governing body or designated person responsible for developing policies on participant health and safety, including a comprehensive, systemic operational plan to ensure the health and safety of the PACE organization's participants (§ 460.62(a)(6)). We expect that an emergency preparedness plan will be an essential component of such a comprehensive, systemic operational plan. However, this regulatory requirement does not guarantee that all PACE organizations have developed a plan that complies with our requirements.

Thus, we expect that all PACE organizations will need to review their current plans and compare them to their risk assessments. PACE organizations will need to update, revise, and, in some cases, develop new sections to complete their emergency preparedness plans.

Based upon our experience with PACE organizations, we expect that the same individuals who were involved in developing the risk assessment will be involved in developing the emergency preparedness plan. However, we expect that it will require more time to complete the plan. We expect that the quality improvement nurse will have primary responsibility for reviewing and developing the PACE organization's emergency preparedness plan. We expect that the program director, home care coordinator, and social worker will review the current plan, provide comments, and assist the quality improvement nurse in developing the final plan. Other staff members will work only on the sections of the plan that will be relevant to their areas of responsibility.

We estimate that for each PACE organization to comply with the requirement for an emergency preparedness plan will require 23 burden hours at a cost of $1,798. We estimate that for all PACE organizations to comply will require 2,737 burden hours (23 burden hours for each PACE Organization × 119 PACE organizations) at a cost of $213,962 ($1,798 estimated cost for each PACE organization × 119 PACE organizations).

TABLE 35—TOTAL COST ESTIMATE FOR A PACE TO DEVELOP AN EMERGENCY PLAN

Position	Hourly wage	Burden hours	Cost estimate
Program Director	$110	4	$440
Medical Director	182	2	364
Home Care Coordinator	64	7	448
Registered Nurse/Quality Improvement	64	6	384
Social Worker	55	2	110
Driver	26	2	52
Total	....	23	1,798

The PACE organizations will also be required to review and update their emergency preparedness plans at least annually. We believe that PACE organizations are already reviewing their emergency preparedness plans periodically. Therefore, we believe compliance with this requirement will constitute a usual and customary business practice for PACE organizations and will not be subject to the PRA in accordance with the implementing regulations of the PRA 5 CFR 1320.3(b)(2).

Section 460.84(b) will require each PACE organization to develop and implement emergency preparedness policies and procedures based on the emergency plan set forth in paragraph (a), the risk assessment at paragraph (a)(1), and the communication plan at paragraph (c). It will also require PACE organizations to review and update these policies and procedures at least annually. At a minimum, we will require that a PACE organization's policies and procedures address the requirements listed at § 460.84(b)(1) through (9).

Current regulations already require that PACE organizations establish, implement, and maintain procedures for managing emergencies and disasters (§ 460.72(c)). The definition of "emergencies" includes medical and nonmedical emergencies, such as natural disasters likely to occur in a PACE organization's area (§ 460.72(c)(2)). In addition, all PACE organizations must have a governing body or a designated person who functions as the governing body responsible for developing policies on participant health and safety (§ 460.62(a)(6)). Thus, we expect that all PACE organizations have some emergency preparedness policies and procedures. However, these requirements do not ensure that all PACE organizations have policies and procedures that will comply with our requirements.

The burden associated with the requirements will be the resources needed to review, revise, and, if needed, develop new emergency preparedness policies and procedures. We expect that the program director, home care coordinator, and quality improvement nurse will be primarily responsible for reviewing, revising, and if needed, developing any new policies and procedures needed to comply with our requirements. We estimate that for each PACE organization to comply with our requirements will require 12 burden hours at a cost of $860. Therefore, based on this estimate, for all PACE organizations to comply will require 1,428 burden hours (12 burden hours for each PACE organization × 119 PACE organizations) at a cost of $102,340 ($860 estimated cost for each PACE organization × 119 PACE organizations).

TABLE 36—TOTAL COST ESTIMATE FOR A PACE TO DEVELOP POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Program Director	$110	2	$220
Home Care Coordinator	64	5	320
Registered Nurse/Quality Improvement	64	5	320
Total		12	860

We proposed that each PACE organization must also review and update its emergency preparedness policies and procedures at least annually. We believe that PACE organizations are already reviewing their emergency preparedness policies and procedures periodically. Thus, compliance with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 460.84(c) will require each PACE organization to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. Each PACE organization will also have to review and update this plan at least annually. The communication plan must include the information set out at § 460.84(c)(1) through (7).

All PACE organizations must have a governing body (or a designated person who functions as the governing body) that is responsible for developing policies on participant health and safety, including a comprehensive, systemic operational plan to ensure the health and safety of the PACE organization's participants (§ 460.62(a)(6)). We expect that the PACE organizations' comprehensive, systemic operational plans will include at least some of our requirements. In addition, it is standard practice in the healthcare industry to maintain contact information for both staff and outside sources of assistance; alternate means of communications in case there is an interruption in phone service to the facility; and a method for sharing information and medical documentation with other healthcare providers to ensure continuity of care for patients. Thus, we expect that all PACE organizations have some type of emergency preparedness communication plan. However, each PACE organization will need to review its current plan and revise or, in some cases, develop new sections to comply with our requirements.

Based on our experience with PACE organizations, we expect that the home care coordinator and the quality assurance nurse will be primarily responsible for reviewing, and if needed, revising, and developing new sections for the communication plan. We estimate that for each PACE organization to comply with the requirements will require 7 burden hours at a cost of $448. Therefore, based on this estimate, for all PACE organizations to comply with this requirement will require 833 burden hours (7 burden hours for each PACE organization × 119 PACE organizations) at a cost of $53,312 ($448 estimated cost for each PACE organization × 119 PACE organizations).

TABLE 37—TOTAL COST ESTIMATE FOR A PACE TO DEVELOP A COMMUNICATION PLAN

Position	Hourly wage	Burden hours	Cost estimate
Home Care Coordinator	$64	4	$256
Registered Nurse/Quality Improvement	64	3	192
Total		7	448

Each PACE organization must also review and update its emergency preparedness communication plan at least annually. We believe that PACE organizations are already reviewing and updating their emergency preparedness communication plans periodically. Thus, we believe compliance with this requirement will constitute a usual and customary business practice for PACE organizations and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 460.84(d) will require PACE organizations to develop and maintain emergency preparedness training and testing programs and review and update those programs at least annually. We proposed that each PACE organization will have to meet the requirements listed at § 460.84(d)(1) and (2).

Section 460.84(d)(1) will require PACE organizations to provide initial training on their emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, contractors, participants, and volunteers, consistent with their expected roles and maintain documentation of this training. PACE organizations will also have to ensure that their staff could demonstrate knowledge of the emergency procedures. Thereafter, PACE organizations will be required to provide this training annually.

Current regulations require PACE organizations to provide periodic orientation and appropriate training to their staffs and participants in emergency procedures (§ 460.72(c)(3)). However, these requirements do not ensure that all PACE organizations will be in compliance with our requirements. Thus, each PACE organization will need to review its current training program and compare the training program to its risk assessment, emergency preparedness plan, policies and procedures, and communication plan. The PACE organization will also need to revise and, in some cases, develop new sections to ensure that its emergency preparedness training program complied with our requirements. We expect that the quality assurance nurse will review all elements of the PACE organization's training program and determine what tasks will need to be performed and what materials will need to be developed to comply with our requirements. We expect that the home care coordinator will work with the quality assurance nurse to develop the revised and updated training program. We estimate that for each PACE organization to comply with the requirements will require 12 burden hours at a cost of $768. Therefore, it will require an estimated 1,428 burden hours (12 burden hours for each PACE organization × 119 PACE organizations) to comply with this requirement at a cost of $91,392 ($768 estimated cost for each PACE organization × 119 PACE organizations).

TABLE 38—TOTAL COST ESTIMATE FOR A PACE TO DEVELOP A TRAINING PROGRAM

Position	Hourly wage	Burden hours	Cost estimate
Home Care Coordinator	$64	3	$192
Registered Nurse/Quality Improvement	64	9	576
Total		12	768

The PACE organizations will also be required to review and update their emergency preparedness training program at least annually. We believe that PACE organizations are already reviewing and updating their emergency preparedness training programs periodically. Therefore, we believe compliance with this requirement will constitute a usual and customary business practice for PACE organizations and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 460.84(d)(2) will require PACE organizations to participate in a full-scale exercise at least annually. They will also be required to conduct one additional exercise of their choice at least annually. PACE organizations will also be required to analyze their responses to, and maintain documentation of, all testing exercises and any emergency events they experienced. If a PACE organization experienced an actual natural or man-made emergency that required activation of its emergency plan, it will be exempt from engaging in a community or individual, facility-based full-scale exercise for 1 year following the onset of the actual event. To comply with these requirements, PACE organizations will need to develop a specific scenario for each drill and exercise. The PACE organizations will also have to develop the documentation necessary for recording and analyzing their response to all testing exercises and emergency events.

Current regulations require each PACE organization to conduct a test of its emergency and disaster plan at least annually (42 CFR 460.72(c)(5)). They also must evaluate and document the effectiveness of their emergency and disaster plans. Thus, PACE organizations already conduct at least one test annually of their plans. We expect that as part of testing their emergency plans annually, PACE organizations will develop a scenario for and document the testing. However, this does not ensure that all PACE organizations will be in compliance with all of our requirements, especially the requirement for conducting a paper-based, tabletop exercise; performing a community-based full-scale exercise; and using different scenarios for the testing exercises.

The 119 PACE organizations will be required to develop scenarios for testing exercises and the documentation necessary to record and analyze their response to all exercises and any emergency events. Based on our experience with PACE organizations, we expect that the same individuals who developed their emergency preparedness training programs will develop the required documentation. We expect the quality improvement nurse will spend more time on these activities than the healthcare coordinator. We estimate that this activity will require 5 burden hours for each PACE organization at a cost of $320. We estimate that for all PACE organizations to comply with these requirements will require 595 burden hours (5 burden hours for each PACE organization × 119 PACE organizations) at a cost of $38,080 ($595 estimated cost for each PACE organization × 119 PACE organizations).

TABLE 39—TOTAL COST ESTIMATE FOR A PACE TO CONDUCT TESTING EXERCISES

Position	Hourly wage	Burden hours	Cost estimate
Home Care Coordinator	$64	4	$256
Registered Nurse/Quality Improvement	64	1	64
Total		5	320

TABLE 40—BURDEN HOURS AND COST ESTIMATES FOR ALL 119 PACE ORGANIZATIONS TO COMPLY WITH THE ICRS CONTAINED IN § 460.84 EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 460.84(a)(1)	0938—New	119	119	14	1,666	**	131,495	131,495
§ 460.84(a)(1)–(4)	0938—New	119	119	23	2,737	**	213,962	213,962
§ 460.84(b)	0938—New	119	119	12	1,428	**	102,340	102,340
§ 460.84(c)	0938—New	119	119	7	833	**	53,312	53,312
§ 460.84(d)(1)	0938—New	119	119	12	1,428	**	91,392	91,392
§ 460.84(d)(2)	0938—New	119	119	5	595	**	38,080	38,080
Totals		119	714		8,687			630,581

** The hourly labor cost is blended between the wages for multiple staffing levels.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 40.

H. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 482.15)

Section 482.15(a) will require hospitals to develop and maintain emergency preparedness plans. We proposed that hospitals be required to review and update their emergency preparedness plans at least annually and meet the requirements set out at § 482.15(a)(1) through (4). Note that we obtain data on the number of hospitals, both accredited and non-accredited, from the CMS CASPER data system, which are updated periodically by the individual states. Due to variations in the timeliness of the data submissions, all numbers are approximate, and the number of accredited and non-accredited hospitals shown may not equal the number of hospitals at the time of this final rule's publication. In addition, some hospitals may have chosen to be accredited by more than one accrediting organization.

There are approximately 4,793 Medicare-certified hospitals. This includes 121 critical access hospitals (CAHs) that have rehabilitation or psychiatric distinct part units (DPUs) as of June 30, 2016 CASPER data. The services provided by CAH psychiatric or rehabilitation DPUs must comply with the hospital Conditions of Participation (CoPs) (42 CFR 485.647(a)). RNHCIs and CAHs that do not have DPUs have been excluded from this number and are addressed separately in this analysis. Of the 4,793 hospitals reported in CMS' CASPER data system, approximately 3,913 are accredited hospitals and the remainder are non-accredited hospitals. Three organizations have accrediting authority for these hospitals: TJC, formerly known as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), the AOA/HFAP, and DNV GL.

Accreditation can substantially affect the burden a hospital will sustain under this final rule. The Joint Commission accredits 3,448 hospitals. Many of our requirements are similar or virtually identical to the standards, rationales, and elements of performance (EPs) required for TJC accreditation. TJC standards, rationales, and elements of performance (EPs) are on the TJC Web site at *http://www.jointcommission.org/*.

The AOA/HFAP and DNV GL hospital accreditation requirements do not emphasize emergency preparedness. In addition, these hospitals account for less than 5 percent of all of the hospitals. Thus, for purposes of determining the burden, we have included the AOA/HFAP-accredited hospitals and the DNV GL-accredited hospitals in with the hospitals that are not accredited. Therefore, unless indicated otherwise, we have analyzed the burden for the 3,448 TJC-accredited hospitals separately from the remaining 1,345 non TJC-accredited hospitals (4,793 hospitals − 3,448 TJC-accredited hospitals).

We have used TJC's "Comprehensive Accreditation Manual for Hospitals: The Official Handbook 2008 (CAMH)" to determine the burden for TJC-accredited hospitals. In the chapter entitled, "Management of the Environment of Care" (EC), hospitals are required to plan for managing the consequences of emergencies (CAMH, Standard EC.4.11, CAMH Refreshed Core, January 2008, p. EC–13a). Individual standards have EPs, which provide the detailed and specific performance expectations, structures, and processes for each standard (CAMH, CAMH Refreshed Core, January 2008, p. HM–6). The EPs for Standard EC.4.11 require, among other things, that hospitals conduct a hazard vulnerability analysis (HVA) (CAMH, Standard EC.4.11, EP 2, CAMH Refreshed Core, January 2008, p. EC–13a). Performing an HVA will require a hospital to identify the events that could possibly affect demand for the hospital's services or the hospital's ability to provide services. A TJC-accredited hospital also must determine the likeliness of the identified risks occurring, as well as their consequences. Thus, we expect that TJC-accredited hospitals already conduct an HVA that complies with our requirements and that any additional tasks necessary to comply will be minimal. Therefore, for TJC-accredited hospitals, the risk assessment requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 482.15(a)(1) will require that hospitals perform a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach. We expect that most non TJC-accredited hospitals have already performed at least some of the work needed for a risk assessment. The Niska and Burt article indicated that most hospitals already have plans for natural disasters. However, many may not have thoroughly documented this activity or performed as thorough a risk assessment as needed to comply with our requirements.

We have not designated any specific process or format for hospitals to use in conducting a risk assessment because we believe that hospitals need the flexibility to determine how best to accomplish this task. However, we expect that hospitals will obtain input from all of their major departments when performing a risk assessment. Based on our experience, we expect that conducting a risk assessment will require the involvement of at least a hospital administrator, the risk management director, the chief medical officer, the chief of surgery, the director of nursing, the pharmacy director, the facilities director, the health information services director, the safety director, the security manager, the community relations manager, the food services director, and administrative support staff. We expect that most of these individuals will attend an initial meeting, review relevant sections of their current risk assessment, prepare and send their comments to the risk management director, attend a follow-up meeting, perform a final review, and approve the new risk assessment.

We expect that the risk management director will coordinate the meetings, review and comment on the current risk assessment, suggest revisions, coordinate comments, develop the new risk assessment, and ensure that the necessary parties approve it. We expect that the hospital administrator will spend more time reviewing the risk assessment than most of the other individuals.

We estimate that the risk assessment will require 34 burden hours to complete at a cost of $4,232 for each non-TJC accredited hospital. There are approximately 1,345 non TJC-accredited hospitals. Therefore, it will require an estimated 45,730 burden hours (34 burden hours for each non TJC-accredited hospitals × 1,345 non TJC-accredited hospitals) for all non TJC-accredited hospitals to comply at a cost of $5,692,040 ($4,232 estimated cost for each non TJC-hospital × 1,345 non TJC-accredited hospitals).

TABLE 41—TOTAL COST ESTIMATE FOR A NON-TJC ACCREDITED HOSPITAL TO DEVELOP AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$172	4	$688
Risk Management Director	104	8	832
Chief Medical Officer/Medical Director	199	2	398
Chief of Surgery	231	2	462
Director of Nursing	104	3	312
Pharmacy Director	142	3	426
Facilities Director	104	3	312
Health Information Services Director	104	2	208
Security Manager	104	2	208
Community Relations Manager	107	2	214
Food Services Manager	70	2	140
Medical Secretary	32	1	32
Total	....	34	4,232

Section 482.15(a)(1) through (4) will require hospitals to develop and maintain emergency preparedness plans. We expect that all hospitals will compare their risk assessments to their emergency plans and revise and, if necessary, develop new sections for their plans. TJC-accredited hospitals must develop and maintain written Emergency Operations Plans (EOPs) (CAMH, Standard EC.4.12, EP 1, CAMH Refreshed Care, January 2008, p. EC–13b). The EOP should describe an "all-hazards" approach to coordinating six critical areas: Communications, resources and assets, safety and security, staff roles and responsibilities, utilities, and patient clinical and support activities during emergencies (CAMH, Standard EC.4.13–EC.4.18, CAMH Refreshed Core, January 2008, pp. EC–13b–EC–13g). Hospitals also must include in their EOP "[r]esponse strategies and actions to be activated during the emergency" and "[r]ecovery strategies and actions designed to help restore the systems that are critical to resuming normal care, treatment and services" (CAMH, Standard EC.4.11, EPs 7 and 8, p. EC–13a). In addition, hospitals are required to have plans to manage "clinical services for vulnerable populations served by the hospital, including patients who are pediatric, geriatric, disabled or have serious chronic conditions or addictions" (CAMH, Standard EC.4.18, EP 2, p. EC–13g). Hospitals also must plan how to manage the mental health needs of their patients (CAMH, Standard EC.4.18, EP 4, EC–13g). Thus, we expect that TJC-accredited hospitals have already developed and are maintaining EOPs that comply with the requirement for an emergency plan in this final rule. If a TJC-accredited hospital needed to complete additional tasks to comply with the requirement, we believe that the burden will be negligible. Therefore, for TJC-accredited hospitals, this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

We expect that most, if not all, non TJC-accredited hospitals already have some type of emergency preparedness plan. The Niska and Burt article noted that the majority of hospitals have plans for natural disasters; incendiary incidents; and biological, chemical, and radiological terrorism. In addition, all hospitals must already meet the requirements set out at 42 CFR 482.41, including emergency power, lighting, gas and water supply requirements as well as specified Life Safety Code provisions. However, those existing plans may not be fully compliant with our requirements. Thus, it will be necessary for non TJC-accredited hospitals to review their current plans and compare them to their risk assessments and revise, update, or, in some cases, develop new sections for their emergency plans.

Based on our experience with hospitals, we expect that the same individuals who were involved in developing the risk assessment will be involved in developing the emergency preparedness plan. However, we estimate that it will require substantially more time to complete an emergency preparedness plan. We estimate that complying with this requirement will require 62 burden hours at a cost of $7,408 for each non TJC-accredited hospital. There are approximately 1,345 non TJC-accredited hospitals. Therefore, based on this estimate, it will require 83,390 burden hours for all non TJC-accredited hospitals (62 burden hours for each non TJC-accredited hospitals × 1,345 non TJC-accredited hospitals) to complete an emergency preparedness plan at a cost of $9,963,760 ($7,408 estimated cost for each non TJC-accredited hospital × 1,345 non TJC-accredited hospitals).

TABLE 42—TOTAL COST ESTIMATE FOR A NON-TJC ACCREDITED HOSPITAL TO CONDUCT A RISK ASSESSMENT

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$172	4	$688
Risk Management Director	104	20	2,080
Chief Medical Officer/Medical Director	199	3	597
Chief of Surgery	231	3	693
Director of Nursing	104	6	624
Pharmacy Director	142	5	710
Facilities Director	104	6	624
Health Information Services Director	104	3	312
Security Manager	104	6	624
Community Relations Manager	107	2	214
Food Services Manager	70	3	210
Medical Secretary	32	1	32
Total	....	62	7,408

Under this final rule, a hospital also will be required to review and update its emergency preparedness plan at least annually. We believe that hospitals already review their emergency preparedness plans periodically. Therefore, we believe compliance with this requirement will constitute a usual and customary business practice for hospitals and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Under § 482.15(b), we will require each hospital to develop and implement emergency preparedness policies and procedures based on its emergency plan set forth in paragraph (a), the risk assessment at paragraph (a)(1), and the communication plan at paragraph (c). We will also require hospitals to review and update these policies and procedures at least annually. At a minimum, we will require that the policies and procedures address the requirements at § 482.15(b)(1) through (8).

We will expect all hospitals to review their emergency preparedness policies and procedures and compare them to their emergency plans, risk assessments, and communication plans. We expect that hospitals will then review, revise, and, if necessary, develop new policies and procedures that comply with our requirements.

The CAMH's chapter entitled, "Leadership" (LD), requires TJC-accredited hospital leaders to "develop policies and procedures that guide and support patient care, treatment, and services." The policies and procedures are to guide all patient care, including during and after emergencies (CAMH, Standard LC.3.90, EP 1, CAMH Refreshed Core, January 2008, p. LD–15). Thus, we expect that TJC-accredited hospitals already have some policies and procedures related to our requirements. In addition to meeting TJC standards, hospitals are required to meet state and local and licensing requirements. Based on these requirements, hospitals have been operating within this framework in the delivery of patient care services. State and local laws require fire, emergency, and safety codes that have an impact on operations during an emergency or a disaster. As discussed later, many of the requirements in § 482.15(b) has a corresponding requirement in the TJC hospital accreditation standards. Hence, we will discuss each section individually.

Section 482.15(b)(1) will require hospitals to have policies and procedures for the provision of subsistence needs for staff and patients, whether they evacuate or shelter in place. TJC-accredited hospitals are required to make plans for obtaining and replenishing medical and non-medical supplies, including food, water, and fuel for generators and transportation vehicles (CAMH, Standard EC.4.14, EPs 1–8 and 10–11, p. EC–13d). In addition, hospitals must identify alternative means of providing electricity, water, fuel, and other essential utility needs in cases when their usual supply is disrupted or compromised (CAMH, Standard EC.4.17, EPs 1–5, p. EC–13f). Thus, we expect that TJC-accredited hospitals will be in compliance with our provision of subsistence requirements in § 482.15(b)(1).

Section 482.15(b)(2) will require hospitals to have policies and procedures to track the location of on-duty staff and sheltered patients in the hospital's care during an emergency. TJC-accredited hospitals must plan for communicating with patients and their families at the beginning of and during an emergency (CAMH, Standard EC.4.13, EPs 1, 2, and 5, p. EC–13c). We expect that TJC-accredited hospitals will be in compliance with § 482.15(b)(2).

Section 482.15(b)(3) will require hospitals to have policies and procedures for a plan for the safe evacuation from the hospital. TJC-accredited hospitals are required to make plans to evacuate patients as part of managing their clinical activities (CAMH, Standard EC.4.18, EP 1, p. EC–13g). They also must plan for the evacuation and transport of patients, as well as their information, medications, supplies, and equipment, to alternative care sites (ACSs) when the hospital cannot provide care, treatment, and services in their facility (CAMH, Standard EC.4.14, EPs 9–11, p. EC–13d). Section 482.15(b)(3) also will require hospitals to have "primary and alternate means of communication with external sources of assistance." TJC-accredited hospitals must plan for communicating with external authorities once the hospital initiates its emergency response measures (CAMH, Standard EC.4.13, EP 4, p. EC–13c). Thus, TJC-accredited hospitals will be in compliance with most of the requirements in § 482.15(b)(3). However, we do not believe these requirements will ensure compliance with the requirement that the hospital establish policies and procedures for staff responsibilities.

Section 482.15(b)(4) will require hospitals to have policies and procedures that address a means to shelter in place for patients, staff, and volunteers who remain at the facility. The rationale for CAMH Standard EC.4.18 states, "a catastrophic emergency may result in the decision to keep all patients on the premises in the interest of safety" (CAMH, Standard EC.4.18, p. EC–13f). We expect that TJC-accredited hospitals will be in compliance with our shelter in place requirement in § 482.15(b)(4).

Section 482.15(b)(5) will require hospitals to have policies and procedures that address a system of medical documentation that preserves patient information, protects the confidentiality of patient information, and ensures that records are secure and readily available. The CAMH chapter entitled "Management of Information" requires TJC-accredited hospitals to have storage and retrieval systems for their clinical/service and hospital-specific information (CAMH, Standard IM.3.10, EP 5, CAMH Refreshed Core, January 2008, p. IM–10) and to ensure the continuity of their critical information "needs for patient care, treatment, and services (CAMH, Standard IM.2.30, Rationale for IM.2.30, CAMH Refreshed Core, January 2008, p. IM–8). They also must ensure the privacy and confidentiality of patient information (CAMH, Standard IM.2.10, CAMH Refreshed Core, January 2008, p. IM–7) and have plans for transporting and tracking patients' clinical information, including transferring information to ACSs (CAMH Standard EC.4.14, EP 11, p. EC–13d and Standard EC.4.18, EP 6, pp. EC–13d and EC–13g, respectively). Therefore, we expect that TJC-accredited hospitals will be in compliance with the requirements we proposed in § 482.15(b)(5).

Section 482.15(b)(6) will require hospitals to have policies and procedures that address the use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of state and federally-designated healthcare professionals to address surge needs during an emergency. TJC-accredited hospitals must already define staff roles and responsibilities in their EOPs and ensure that they train their staffs for their assigned roles (CAMH, Standard EC.4.16, EPs 1 and 2, p. EC–13e). The rationale for Standard EC.4.15 indicates that the "hospital determines the type of access and movement to be allowed by . . . emergency volunteers . . . when emergency measures are initiated." In addition, in the chapter entitled "Medical Staff" (MS), hospitals "may grant disaster privileges to volunteers that are eligible to be licensed independent practitioners" (CAMH, Standard MS.4.110, CAMH Refreshed Care, January 2008, p. MS–27). Finally, in the chapter entitled "Management of Human Resources" (HR), hospitals "may assign disaster responsibilities to volunteer practitioners" (CAMH, Standard HR.1.25, CAMH Refreshed Core, January 2008, p. HR–5). Although TJC accreditation requirements partially address our requirements, we do not believe these requirements will ensure compliance with all requirements in in § 482.15(b)(6).

Section 482.15(b)(7) will require hospitals to have policies and procedures that will address the development of arrangements with other hospitals or other providers to receive patients in the event of limitations or cessation of operations to ensure continuity of services to hospital patients. TJC-accredited hospitals must plan for the sharing of resources and assets with other healthcare organizations (CAMH, Standard EC.4.14, EPs 7 and 8, p. EC–13d). However, we will not expect TJC-accredited hospitals to be substantially in compliance with the requirements we proposed in § 482.15(b)(7) based on compliance with TJC accreditation standards alone.

Section 482.15(b)(8) will require hospitals to have policies and procedures that address the hospital's role under an "1135 waiver" (that is, a waiver of some federal rules in accordance with § 1135 of the Social Security Act) in the provision of care and treatment at an ACS identified by emergency management officials. TJC-accredited hospitals must already have plans for transporting patients, as well as their associated information, medications, equipment, and staff to ACSs when the hospital cannot support their care, treatment, and services on site (CAMH, Standard EC.4.14, EPs 10 and 11, p. EC–13d). We expect that TJC-accredited hospitals will be in compliance with the requirements we proposed in § 482.15(b)(8).

In summary, we expect that TJC-accredited hospitals have developed and are maintaining policies and procedures that will comply with the requirements in § 482.15(b), except for § 482.15(b)(3), (6), and (7). Later we will discuss the burden on TJC-accredited hospitals with respect to these provisions. We expect that any modifications that TJC-accredited hospitals will need to make to comply with the remaining requirements will not impose a burden above that incurred as part of usual and customary business practices. Thus, with the exception of the requirements set out at § 482.15(b)(3), (6), and (7), we believe the requirements constitute usual and customary business practices and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

The burden associated with § 482.15(b)(3), (6), and (7) will be the resources required to develop written policies and procedures that comply with the requirements. We expect that the risk management director will review the hospital's policies and procedures initially and make recommendations for revisions and development of additional policies or procedures. We expect that representatives from the hospital's major departments will make revisions or draft new policies and procedures based on the administrator's recommendation. The appropriate parties will then need to compile and disseminate these new policies and procedures. We estimate that complying with these requirements will require 17 burden hours for each TJC-accredited hospital at a cost of $2,061. For all 3,448 TJC-accredited hospitals to comply with these requirements will require an estimated 58,616 burden hours (17 burden hours for each TJC-accredited hospital × 3,448 TJC-accredited hospitals) at a cost of $7,106,328 ($2,061 estimated cost for each TJC-accredited hospital × 3,448 TJC-accredited hospitals).

TABLE 43—TOTAL COST ESTIMATE FOR A TJC-ACCREDITED HOSPITAL TO DEVELOP POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$172	2	$344
Risk Management Director	104	4	416
Chief Medical Officer/Medical Director	199	1	199

TABLE 43—TOTAL COST ESTIMATE FOR A TJC-ACCREDITED HOSPITAL TO DEVELOP POLICIES AND PROCEDURES—Continued

Position	Hourly wage	Burden hours	Cost estimate
Chief of Surgery	231	1	231
Director of Nursing	104	2	208
Pharmacy Director	142	1	142
Facilities Director	104	1	104
Health Information Services Director	104	1	104
Security Manager	104	1	104
Community Relations Manager	107	1	107
Food Services Manager	70	1	70
Medical Secretary	32	1	32
Total	....	17	2,061

The 1,345 non TJC-accredited hospitals will need to review their policies and procedures, ensure that their policies and procedures accurately reflect their risk assessments, emergency preparedness plans, and communication plans, and incorporate any of our requirements into their policies and procedures. We expect that the risk management director will coordinate the meetings, review and comment on the current policies and procedures, suggest revisions, coordinate comments, develop the policies and procedures, and ensure that the necessary parties approve it. We expect that the hospital administrator will spend more time reviewing the policies and procedures than most of the other individuals.

We estimate that complying with this requirement will require 33 burden hours for each non TJC-accredited hospital at an estimated cost of $3,831. Based on this estimate, for all 1,345 non TJC-accredited hospitals to comply with these requirements will require 44,385 burden hours (33 burden hours for each non TJC-accredited hospital × 1,345 non TJC-accredited hospitals) at a cost of $5,152,695 ($3,831 estimated cost for each non TJC-accredited hospital × 1,345 non TJC-accredited hospitals).

TABLE 44—TOTAL COST ESTIMATE FOR A NON TJC-ACCREDITED HOSPITAL TO DEVELOP POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$172	3	$516
Risk Management Director	104	10	1,040
Chief Medical Officer/Medical Director	199	1	199
Chief of Surgery	231	1	231
Director of Nursing	104	6	624
Pharmacy Director	142	2	284
Facilities Director	104	3	312
Health Information Services Director	104	1	104
Security Manager	104	3	312
Community Relations Manager	107	1	107
Food Services Manager	70	1	70
Medical Secretary	32	1	32
Total	....	33	3,831

In addition, we expect that there will be a burden as a result of § 482.15(b)(7). Section 482.15(b)(7) will require hospitals to develop and maintain policies and procedures that address a hospital's development of arrangements with other hospitals and other providers to receive patients in the event of limitations or cessation of operations to ensure continuity of services to hospital patients. We expect that hospitals will base those arrangements on written agreements between the hospital and other hospitals and other providers. Thus, in addition to the burden related to developing the policies and procedures, hospitals will also sustain a burden related to developing the written agreements related to those arrangements.

All 4,793 hospitals will need to identify other hospitals and other providers with which they could have agreements, negotiate and draft the agreements, and obtain all necessary authorizations for the agreements. For the purpose of determining the burden, we will assume that hospitals will have written agreements with two other hospitals and other providers. Based on our experience with hospitals, we expect that complying with this requirement will primarily require the involvement of the hospital's administrator and risk management director. We also expect that a hospital attorney will assist with drafting the agreements and reviewing those documents for any legal implications. We estimate that complying with this requirement will require 8 burden hours for each hospital at an estimated cost of $1,037. Thus, it will require an estimated 38,344 burden hours (8 burden hours for each hospital × 4,793 hospitals) for all hospitals to comply with this requirement at a cost of $4,970,341 ($1,037 estimated cost for each hospital × 4,793 hospitals).

TABLE 45—TOTAL COST ESTIMATE FOR A HOSPITAL, WITH WRITTEN AGREEMENTS WITH OTHER HOSPITALS OR PROVIDERS, TO DEVELOP POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$172	2	$344
Risk Management Director	104	3	312
Attorney	127	3	381
Total		8	1,037

Section 482.15(b) will also require hospitals to review and update their emergency preparedness policies and procedures at least annually. We believe hospitals are already reviewing and updating their emergency preparedness policies and procedures periodically. Thus, we believe compliance with this requirement will constitute a usual and customary business practice for both TJC-accredited and non TJC-accredited hospitals and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2). Section 482.15(c) will require each hospital to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. The plan will have to be reviewed and updated at least annually. The communication plan will have to include the information listed at § 482.15(c)(1) through (7).

We expect that all hospitals currently have some type of emergency preparedness communication plan. We expect that under this final rule, hospitals will review their current communication plans, compare them to their emergency preparedness plans and emergency policies and procedures, and revise their communication plans, as necessary. It is standard practice for healthcare facilities to maintain contact information for staff and outside sources of assistance; have alternate means of communication in case there is an interruption in phone service to the facility; and have a method for sharing information and medical documentation with other healthcare providers to ensure continuity of care for patients. However, under this final rule, all hospitals will need to review and update their plans to ensure compliance with our requirements.

TJC-accredited hospitals are required to establish emergency communication strategies (CAMH, Standard EC.4.13, p. EC–13b). In addition, TJC-accredited hospitals are specifically required to ensure communication with staff, external authorities, patients, and their families (CAMH, Standard EC.4.13, EPs 1–5, p. EC–13c). TJC-accredited hospitals also are required to establish "back-up communications systems and technologies" for such activities (CAMH, Standard EC.4.13, EP 14, p. EC–13c). Moreover, TJC-accredited hospitals are required specifically to define "the circumstances and plans for communicating information about patients to third parties (such as other healthcare organizations) . . ." (CAMH, Standard EC.4.13, EP 12, p. EC–13c). Thus, we expect that that TJC-accredited hospitals will be in compliance with § 482.15(c)(1) through (4). In addition, the rationale for EC.4.13 states, "the hospital maintains reliable surveillance and communications capability to detect emergencies and communicate response efforts to hospital response personnel, patient and their families, and external agencies (CAMH, Standard EC.4.13, pp. EC–13b—13c). We expect that most, if not all, TJC-accredited hospitals will be in compliance with § 482.15(c)(5) through (7). Therefore, we expect that TJC-accredited hospitals already have developed and are currently maintaining emergency communication plans that will satisfy the requirements contained in § 482.15(c). Therefore, we believe compliance with this requirement will constitute a usual and customary business practice and will not be subject to PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Most, if not all, non TJC-accredited hospitals will be substantially in compliance with § 482.15(c)(1) through (4). However, non TJC-accredited hospitals will need to review, update, and in some cases, develop new sections for their emergency communication plans to ensure they are in compliance with all of the requirements in this section. We expect that this activity will require the involvement of the hospital's administrator, the risk management director, the facilities director, the health information services director, the security manager, and administrative support staff. We estimate that complying with this requirement will require 10 burden hours at a cost of $1,111 for each of the 1,345 non TJC-accredited hospitals. Therefore, based on this estimate, for non TJC-accredited hospitals to comply with this requirement will require 13,450 burden hours (10 burden hours for each non TJC-accredited hospital × 1,345 non TJC-accredited hospitals) at a cost of $1,494,295 ($1,068 estimated cost for each non TJC-accredited hospital × 1,345 non TJC-accredited hospitals).

TABLE 46—TOTAL COST ESTIMATE FOR A NON TJC-ACCREDITED HOSPITAL TO DEVELOP A COMMUNICATION PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$172	1	$172
Risk Management Director	104	4	416
Director of Nursing	104	1	104
Facilities Director	104	1	104
Health Information Services Director	104	1	104
Security Manager	104	1	104
Community Relations Manager	107	1	107
Total		10	1,111

Section 482.15(c) also will require hospitals to review and update their emergency preparedness communication plans at least annually. We believe that hospitals are already reviewing and updating their emergency preparedness communication plans periodically. Therefore, we believe compliance with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 482.15(d) will require hospitals to develop and maintain emergency preparedness training and testing programs and review and update those plans at least annually. The hospital will be required to meet the requirements in § 482.15(d)(1) and (2).

Section 482.15(d)(1) will require hospitals to provide initial and thereafter annual training on their emergency preparedness policies and procedures to all and new existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles. Hospitals must also maintain documentation of all of this training.

The burden for § 482.15(d)(1) will be the time and effort necessary to develop a training program and the materials needed for the required initial and annual training. We expect that all hospitals will review their current training programs and compare them to their risk assessments, emergency plans, policies and procedures, and communication plans as set forth in § 482.15(a)(1), (a), (b), and (c), respectively. Hospitals will need to revise and, if necessary, develop new sections or material to ensure that their training programs comply with our requirements.

TJC-accredited hospitals are required to define staff roles and responsibilities in their EOP and train their staff for their assigned roles during emergencies (CAMH, EC.4.16, EPs 1–2, p. EC–13e). In addition, the TJC-accredited hospitals are required to provide an initial orientation, which includes information that the hospital has determined are key elements the staff need before they provide care, treatment, or services to patients (CAMH, Standard HR.2.10, EPs 1–2, CAMH Refreshed Core, January 2008, p. HR–10). We will expect that an orientation to the hospital's EOP will be part of this initial training. TJC-accredited hospitals also must provide on-going training to their staff, including training on specific job-related safety (CAMH, Standard HR–2.30, EP 4, CAMH Refreshed Core, January 2008, p. HR–11), and we expect that emergency preparedness is part of such on-going training.

Although TJC requirements do not specifically address training for individuals providing services under arrangement or training for volunteers consistent with their expected roles, it is standard practice for healthcare facilities to provide some type of training to all personnel, including those providing services under contract or arrangement and volunteers. If a hospital does not already provide such training, we will expect the additional burden to be negligible. Thus, for the TJC-accredited hospitals, the requirements will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Based on our experience with non TJC-accredited hospitals, we expect that the non TJC-accredited hospitals have some type of emergency preparedness training program and provide training to their staff regarding their duties and responsibilities under their emergency plans. However, under this final rule, non TJC-accredited hospitals will need to compare their existing training programs with their risk assessments, emergency preparedness plans, policies and procedures, and communication plans. They also will need to revise, update, and, if necessary, develop new sections and new material for their training programs.

There are many ways in which a hospital may develop a training program. For example, to develop their training programs, hospitals could draw upon the resources of federal, state, and local emergency preparedness agencies, as well as state and national healthcare associations and organizations. Hospitals could also participate in a local healthcare coalition, a partnership with other hospitals, healthcare facilities and local health departments to develop the necessary training. In addition, hospitals could develop partnerships with other hospitals and healthcare facilities to develop the necessary training. Some hospitals might also choose to purchase off-the-shelf emergency training programs or hire consultants to develop the programs for them. However, because many hospitals have a hospital emergency manager and safety office, we anticipate that the training program would likely be developed using the hospital's own staff. It is our experience with hospitals that a majority of them conduct some type of preparedness activities and training and, as such, are most likely to have staff versed in these issues that can assist with training. Additionally, hospitals and other healthcare providers commonly participate in trainings that are provided by their local healthcare coalition, local and state public health and emergency management agencies conducting community based exercises (for example, American Red Cross). The estimation of a burden for these requirements is based on this assumption.

Based on our experience with hospitals, we expect that complying with this requirement will require the involvement of the hospital administrator, the risk management director, a healthcare trainer, and administrative support staff. We estimate that it will require 40 burden hours for each hospital to develop an emergency preparedness training program at a cost of $3,000 for each non TJC-accredited hospital. We estimate that it will require 53,800 burden hours (40 burden hours for each non TJC-accredited hospital × 1,345 non TJC-accredited hospitals) to comply with this requirement at a cost of $4,035,000 ($3,000 estimated cost for each hospital × 1,345 non TJC-accredited hospitals).

TABLE 47—TOTAL COST ESTIMATE FOR A NON TJC-ACCREDITED HOSPITAL TO DEVELOP A TRAINING PROGRAM

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$172	2	$344
Risk Management Director	104	6	624
Healthcare Trainer (Registered Nurse)	68	28	1,904
Medical Secretary	32	4	128
Total		40	3,000

Section 482.15(d) will also require hospitals to review and update their emergency preparedness training program at least annually. We believe that hospitals are already reviewing and updating their emergency preparedness training programs periodically. Thus, we believe compliance with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Hospitals also will be required to maintain documentation of their training. Based on our experience, we believe it is standard practice for hospitals to document the training they provide to their staff, individuals providing services under arrangement, and volunteers. Therefore, we believe compliance with this requirement will constitute a usual and customary business practice for the hospitals and not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 482.15(d)(2) will also require hospitals to participate in a full-scale exercise and one additional exercise of their choice at least annually. Hospitals also will be required to analyze their responses to, and maintain documentation of, all exercises and emergency events. If a hospital experienced an actual emergency which required activation of its emergency plan, it will be exempt from the requirement for a community or individual, facility-based disaster drill for 1 year following the onset of the emergency (§ 482.15(d)(2)(ii)). Thus, to satisfy the burden for these requirements, hospitals will need to develop a scenario for each exercise, as well as the documentation necessary for recording what happened. If a hospital participated in a full-scale exercise, it probably will not need to develop a scenario for that drill. However, for the purpose of determining the burden, we will assume that hospitals will need to develop at least two scenarios annually, one for each testing exercise requirement.

TJC-accredited hospitals are required to test their EOP twice a year (CAMH, Standard EC.4.20, EP 1, p. EC–14a). In addition, TJC-accredited hospitals must analyze all exercises, identify deficiencies and areas for improvement, and modify their EOPs in response to the analysis of those tests (CAMH, Standard EC.4.20, EPs 15–17, p. EC–14b). Therefore, we expect that TJC-accredited hospitals have already developed scenarios for testing exercises and have the documentation needed for the analysis of their responses. We expect that it will be a usual and customary business practice for the TJC-accredited hospitals to comply with the requirement to prepare scenarios for emergency preparedness testing exercises and to develop the necessary documentation. Thus, we believe compliance with this requirement will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Based on our experience with non TJC-accredited hospitals, we expect that the remaining non TJC-accredited hospitals have some type of emergency preparedness training program and that most, if not all, of them already conduct some type of drill or exercise to test their emergency preparedness plans. In addition, many hospitals participate in drills and exercises held by their communities, counties, and states. A 2006 study of 678 hospitals found that 88 percent of the participating hospitals were engaged in community-wide emergency preparedness drills and exercises (Braun BI, Wineman NV, Finn NL, Barbera JA, Schmaltz SP, Loeb JM. Integrating hospitals into community emergency preparedness planning. Ann Intern Med. 2006 Jun;144(11):799–811. PubMed PMID: 16754922.) We also expect that many of these hospitals have already developed the required documentation for recording the events, and analyzing their responses to, their testing exercises and emergency events. However, we do not believe that all non-TJC accredited hospitals will be in compliance with our requirements. Thus, we will analyze the burden for non TJC-accredited hospitals.

The non TJC-accredited hospitals will be required to develop scenarios for the testing exercises and the documentation necessary to record and analyze their responses to the exercises and emergency events. Based on our experience with hospitals, we expect that the same individuals who developed the emergency preparedness training program will develop the scenarios for the testing exercises and the accompanying documentation. We expect that the healthcare trainer will spend more time developing the scenarios and documentation. Thus, for each of the 1,345 non TJC-accredited hospitals to comply with these requirements, we estimate that it will require 9 burden hours at a cost of $752. Based on this estimate, for all 1,345 non TJC-accredited hospitals to comply will require 12,105 burden hours (9 burden hours for each non TJC-accredited hospital × 1,345 non TJC-accredited hospitals) at a cost of $1,011,440 ($752 estimated cost for each non TJC-accredited hospital × 1,345 non TJC-accredited hospital).

TABLE 48—TOTAL COST ESTIMATE FOR A NON TJC-ACCREDITED HOSPITAL TO CONDUCT TESTING

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$172	1	$172
Risk Management Director	104	2	208
Healthcare Trainer (RN)	68	5	340
Medical Secretary	32	1	32
Total		9	752

TABLE 49—BURDEN HOURS AND COST ESTIMATES FOR ALL 4,793 HOSPITALS TO COMPLY WITH THE ICRS CONTAINED IN § 482.15 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 482.15(a)(1)	0938—New	1,345	1,345	36	45,730	**	5,692,040.00	5,692,040.00
§ 482.15(a)(1)–(4)	0938—New	1,345	1,345	62	83,390	**	9,963,760.00	9,963,760.00
§ 482.15(b) (TJC-accredited)	0938—New	3,448	3,448	17	58,616	**	7,106,328.00	7,106,328.00

TABLE 49—BURDEN HOURS AND COST ESTIMATES FOR ALL 4,793 HOSPITALS TO COMPLY WITH THE ICRS CONTAINED IN § 482.15 CONDITION: EMERGENCY PREPAREDNESS—Continued

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 482.15(b) (Non TJC-accredited)	0938—New	1,345	1,345	33	44,385	**	5,152,695.00	5,152,695.00
§ 482.15(b)(7)	0938—New	4,793	4,793	8	38,344	**	4,970,341	4,970,341
§ 482.15(c)	0938—New	1,345	1,345	10	13,450	**	1,494,295.00	1,494,295.00
§ 482.15(d)(1)	0938—New	1,345	1,345	40	53,800	**	4,035,000.00	4,035,000.00
§ 482.15(d)(2)	0938—New	1,345	1,345	9	12,105	**	1,011,440.00	1,011,440.00
Totals		9,586	16,311		349,820			39,425,899.00

** The hourly labor cost is blended between the wages for multiple staffing levels.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 49.

I. ICRs Regarding Condition of Participation: Emergency Preparedness for Transplant Centers (§ 482.78)

As discussed in section II.I. of this final rule, we have revised our requirements for transplant centers. Section 482.78 will require that transplant programs be included in the emergency preparedness planning and the emergency preparedness program for the hospital in which it is located. We note that a transplant center is not individually responsible for the emergency preparedness requirements set forth in § 482.15, except as detailed. Section 482.78(a) will require transplant centers to have policies and procedures that address emergency preparedness. Section 482.78(b) will require transplant centers to develop and maintain mutually-agreed upon protocols that address the duties and responsibilities of the transplant center, the hospital in which the transplant center is located, and the OPO during an emergency.

All of the Medicare-approved transplant centers are located within hospitals and, as part of the hospital, should be included in the hospital's emergency preparedness plans. We expect that since transplants are part of the hospital, they are usually involved in the hospital's programs as part of their normal business practices. Thus, compliance with these requirements will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2). We refer readers to the discussion in section H above regarding the burden estimate for hospitals.

J. ICRs Regarding Emergency Preparedness (§ 483.73)

1. Discussion of Omnibus Budget Reconciliation Act of 1987 Waiver

Section 483.73 sets forth the emergency preparedness requirements for long term care (LTC) facilities. We would usually be required to estimate the information collection requirements (ICRs) for these requirements in accordance with chapter 35 of title 44, United States Code. However, sections 4204(b) and 4214(d), which cover skilled nursing facilities (SNFs) and nursing facilities (NFs), respectively, of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) provide for a waiver of PRA requirements for the regulations that implement the OBRA '87 requirements. Section 1819(d) of the Act, as implemented by section 4201 of OBRA '87, requires that SNFs "be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident (consistent with requirements established under subsection (f)(5))." Section 1819(f)(5)(C) of the Act, requires the Secretary to establish criteria for assessing a SNF's compliance with the requirement in subsection (d) with respect for disaster preparedness. Nursing facilities have the same requirement in sections 1919(d) and (f)(5)(C) of the Act, as implemented by OBRA '87.

All of the requirements in this rule relate to disaster preparedness. We believe this waiver applies to those revisions we have made to existing requirements in part 483, subpart B. Thus, the ICRs for the requirements in § 483.73 are not subject to the PRA. However, the waiver does not apply to the requirements of Executive Orders 12866 and 13563 under the Regulatory Impact Analysis (RIA) section. Therefore, to provide readers with sufficient context regarding the RIA discussion of the estimated costs to LTC facilities associated with this final rule, we have provided a discussion of the ICRs for LTC facilities in this COI section. We note that the estimates discussed in this section are not included in Table 128 "Total Burden Hour Estimates for All Providers and Suppliers to Comply with the ICRs Contained in the Final Rule: Emergency Preparedness", per the wavier discussed previously. Emergency preparedness plan that must be reviewed and updated at least annually. The plan will have to meet the requirements set out at § 483.73(a)(1) through (4).

Section 483.73(a)(1) requires LTC facilities to develop documented, facility-based and community-based-risk assessments utilizing an all-hazards approach. We expect that all LTC facilities will need to identify the medical and non-medical emergency events they could experience in their facilities themselves and the communities in which they are located. We expect that in performing a risk assessment, a LTC facility will need to consider its physical location, the geographic area in which it is located, and its resident population.

The burden associated with this requirement will be the time and effort necessary to perform a thorough risk assessment that complies with the requirements of this final rule. Existing requirements for LTC facilities already mandate that LTC facilities have "detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing residents" (see existing § 483.75(m)(1)). We expect that all LTC facilities already have performed some type of risk assessment during the process of developing their emergency and/or disaster plans and procedures. However, these risk assessments may not be as thorough as we require in this final rule, nor address all of the elements required by § 483.73(a)(1). With the exception of severe weather, the existing requirements at § 483.75(m)(1) discussed previously address emergencies and disasters that primarily arise within, or closely surrounding, a LTC facility. In addition, the existing regulations do not specifically require LTC facilities to plan for man-made disasters. Therefore, we expect that under this final rule, all LTC facilities will need to conduct a review of their current risk assessments and then perform the necessary tasks to ensure that their risk assessments comply with the requirements.

We have not identified any specific process or format for LTC facilities to use in conducting their risk assessments because we believe that they need maximum flexibility in determining the best way for their facilities to accomplish this task. However, we expect that in the process of developing a risk assessment, healthcare institutions should include representatives from, or obtain input from, all of their major departments. Based on our experience with LTC facilities, we expect that reviewing, revising, and updating a facility's existing risk assessment will require the involvement of the LTC facility's administrator, director of nursing, and the facilities director. We expect that these individuals will attend an initial meeting, review relevant sections of the previous assessment, if any, develop comments and recommendations, attend a follow-up meeting, perform a final review along with the administrator, and approve the new risk assessment.

In addition, we expect that the administrator will likely coordinate the meetings, perform an initial review of the current risk assessment, provide a critique of the risk assessment, offer suggested revisions, coordinate comments, develop a new risk assessment, and ensure that the necessary parties approve the new risk assessment. Therefore, we expect that the administrator will spend more time than the other participants working on the risk assessment.

We estimate that complying with this requirement will require 8 burden hours at a cost of $692. There are 15,699 LTC facilities in the United States. Therefore, it will require an estimated 125,592 burden hours (8 burden hours for each LTC facility × 15,699 LTC facilities) for all LTC facilities to comply with this requirement at a cost of $10,863,708 ($692 estimated cost for each LTC facility × 15,699 LTC facilities).

TABLE 50—TOTAL COST ESTIMATE FOR A LTC FACILITY TO DEVELOP A RISK ASSESSMENT

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$85.00	4	$340.00
Director of Nursing	85.00	2	170.00
Facilities Director	91.00	2	182.00
Totals		8	692.00

After conducting the risk assessment, each LTC facility will then have to develop and maintain an emergency preparedness plan that addresses the requirements in § 483.73(a)(1)–(4) and review and update this plan at least annually. Existing requirements for LTC facilities require them to have "detailed written plans and procedures to meet all potential emergencies and disasters" (see existing § 483.75(m)(1)). We expect all LTC facilities already have some type of emergency preparedness and/or disaster plan. However, as discussed previously, we expect these plans and procedures will primarily cover disasters and emergencies that will affect the facilities themselves and, with the exception of severe weather, not necessarily the communities in which they are located. We also expect that all LTC facilities will need to review their current plans, compare them to their revised risk assessments, and update, revise, and, if necessary, develop new sections for their plans to ensure their emergency plans address the risks identified in their risk assessments and the specific elements we are issuing in this final rule.

The burden associated with this requirement will be the resources needed to review, revise, and, if needed, develop new sections for the LTC facility's existing emergency plan. Based upon our experience with LTC facilities, we expect that the same individuals who were involved in the risk assessment will be involved in these activities. We also expect these tasks will require more time to complete than the risk assessment.

We expect that the administrator, director of nursing, and the facilities director will have to attend an initial meeting, review the facility's current emergency preparedness plan, develop comments and recommendations, attend a follow-up meeting, perform a final review, and approve the new emergency preparedness plan. We expect that the administrator will develop the emergency preparedness plan and ensure that the necessary parties approved it. We also expect that the administrator will spend more time than the other participants reviewing and working on the emergency preparedness plan.

We estimate that complying with this requirement will require 12 burden hours at a cost of $1,038 for each LTC facility. There are 15,699 LTC facilities. Therefore, it will require an estimated 188,388 burden hours (12 burden hours for each LTC facility × 15,699 LTC facilities) to complete the plan at a cost of $ ($1,038 estimated cost for each LTC facility × 15,699 LTC facilities).

TABLE 51—TOTAL COST ESTIMATE FOR A LTC FACILITY TO DEVELOP AN EMERGENCY PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$85.00	6	$510.00
Director of Nursing	85.00	3	255.00
Facilities Director	91.00	3	273.00
Totals		12	1,038.00

We require LTC facilities to review and update their emergency preparedness plans at least annually. The current emergency preparedness requirements for LTC facilities mandate that they "periodically review the procedures with their existing staff" (§ 483.75(m)(2)). We also expect that all LTC facilities will review and update their emergency preparedness plans annually. Thus, compliance with this requirement will constitute a usual and customary business practice for LTC facilities and will not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Section 483.73(b) requires each LTC facility to develop and maintain emergency preparedness policies and procedures based on their emergency preparedness plan, risk assessment, and communication plan as set forth at § 483.73(a), (a)(1), and (c), respectively. LTC facilities are also required to review and update these policies and procedures at least annually. These policies and procedures will have to address, at a minimum, the requirements set forth at § 483.73(b)(1) through (8).

We expect that all LTC facilities have some emergency preparedness policies and procedures in place because existing regulations require them to have written disaster and emergency preparedness plans and procedures that address all potential disasters and emergencies (see exiting § 483.75(m)(1)). However, under this final rule, all LTC facilities will need to review their policies and procedures, assess whether their policies and procedures incorporate all the elements of their emergency preparedness plan, and if necessary, take the appropriate steps to ensure that their policies and procedures encompass the requirements in this final rule.

The burden associated with these requirements will be the time and effort necessary to review, revise, and, if necessary, develop new emergency policies and procedures. We expect that the administrator, the director of nursing, and the facilities director will be involved with reviewing, revising, and, if needed, developing any new policies and procedures. The administrator will brief any other staff and create assignments for purposes of making necessary revisions or drafting new policies and procedures and disseminate them to the appropriate parties. We estimate that complying with this requirement will require 10 burden hours at a cost of $868. Therefore, for all LTC facilities to comply with this requirement will require an estimated 156,990 burden hours (10 burden hours for each LTC facility × 15,699 LTC facilities) at a cost of $13,626,732 ($868 estimated cost for each LTC facility × 15,699 LTC facilities).

TABLE 52—TOTAL COST ESTIMATE FOR A LTC FACILITY TO DEVELOP POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$85.00	4	$340.00
Director of Nursing	85.00	3	255.00
Facilities Director	91.00	3	273.00
Totals		10	868.00

LTC facilities will be required to review and update their emergency preparedness policies and procedures at least annually. We believe that LTC facilities already review their policies and procedures periodically. Hence, these activities will constitute a usual and customary business practice for LTC facilities and will not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Section 483.73(c) will require each LTC facility to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. The LTC facility will also have to review and update its plan at least annually. The communication plan will have to include the information listed in § 483.73(c)(1) through (7).

We expect that all LTC facilities will compare their current emergency preparedness communications plans, if they have one, to these requirements. The LTC facilities will then need to perform any tasks necessary to ensure that their communication plans were documented and in compliance with these requirements.

We expect that all LTC facilities will have some type of emergency preparedness communication plan. Existing requirements for LTC facilities already require them to have written disaster plans and procedures (see existing § 483.75(m)(1)). Since the ability to communicate with staff, residents' families, and external sources of assistance during an emergency is critical for all healthcare organizations, we believe that communication will be an integral part of any LTC facility's disaster plan. In addition, it is standard practice for healthcare organizations to maintain contact information for their staff and for outside sources of assistance; alternate means of communications in case there is a disruption in phone service to the facility; and a method for sharing information and medical documentation with other healthcare providers to ensure continuity of care for their residents. Thus, we expect that all LTC facilities already comply with the requirements of § 483.73(c)(1) through (3). However, we also expect that many LTC facilities may not have formal, written emergency preparedness communication plans or their plans may not be in compliance with the elements required in § 483.73(c)(4) through (7). Therefore, we expect that under this final rule, all LTC facilities will need to review, update, and in some cases, develop new sections for their emergency communication plans, to ensure those plans include all of these elements.

The burden associated with complying with this requirement will be the resources needed to review, update, and, if necessary, develop new sections for the LTC facility's existing communication plans. Based upon our experience with LTC facilities, we expect that satisfying the requirements of this section will require the involvement of the LTC facility's administrator and the director of nursing. We estimate that complying with this requirement will require 6 burden hours for each facility at a cost of $510. For all LTC facilities to comply with this requirement will require an estimated 94,194 burden hours (6 burden hours for each LTC facility × 15,699 LTC facilities) at a cost of $8,006,490 ($510 estimated cost for each LTC facility × 15,699 LTC facilities).

TABLE 53—TOTAL COST ESTIMATE FOR A LTC FACILITY TO DEVELOP POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$85.00	3	$255.00
Director of Nursing	85.00	3	255.00
Totals	....	6	510.00

LTC facilities will also have to review and update its emergency preparedness communication plan at least annually. We believe that LTC facilities already review and update their plans and procedures periodically. Thus, the requirement for an annual review of the emergency preparedness communications plan constitutes a usual and customary business practice for LTC facilities and will not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Section 483.73(d) will require LTC facilities to develop and maintain emergency preparedness training and testing programs. These training and testing programs will have to be reviewed and updated at least annually. LTC facilities will have to comply with the requirements in § 483.73(d)(1) and (2).

With respect to § 483.73(d)(1), each LTC facility will have to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of that training. Thereafter, each LTC facility will have to provide the training at least annually.

Existing requirements for LTC facilities require facilities to "train all employees in emergency procedures when they begin to work in the facility" and "periodically review the procedures with existing staff" (See existing § 483.75(m)(2)). Therefore, we expect that LTC facilities already provide some type of emergency preparedness training program for new employees, as well as ongoing training for all staff. However, to ensure compliance with the requirements of this final rule, all LTC facilities will need to review their current training programs to ensure that they met all of the requirements in this final rule.

Each LTC facility will need to compare its current emergency preparedness training program's contents to its updated emergency preparedness plan, risk assessment, policies and procedures, and communication plan and then review, revise, and, if necessary, develop new sections for its training program to ensure that it complied with these requirements.

The burden associated with complying with this requirement will be the time and effort necessary for a LTC facility to compare its current emergency preparedness training program's contents to its updated emergency preparedness plan, risk assessment, policies and procedures, and communication plan and then review, revise, and, if necessary, develop new sections for its training program to ensure that it complies with the requirements of this final rule. We believe that these activities will require the involvement of an administrator and the director of nursing. We expect that the director of nursing will likely spend more time than the administrator working on the training program. We estimate that complying with this requirement will require 10 burden hours for each LTC facility at an estimated cost of $850. For all 15,699 LTC facilities to comply with this requirement, it will require an estimated 156,990 burden hours (10 burden hours for each LTC facility × 15,699 LTC facilities) at a cost of $13,344,150 ($850 estimated cost for each LTC facility × 15,699 LTC facilities).

TABLE 54—TOTAL COST ESTIMATE FOR A LTC FACILITY TO CONDUCT TRAINING

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$85.00	2	$170.00
Director of Nursing	85.00	8	680.00
Totals	....	10	850

Each LTC facility will be required to review and update its emergency preparedness training program at least annually. We believe that LTC facilities already review and update their training programs periodically. Thus, compliance with this requirement will constitute a usual and customary business practices for LTC facilities and will not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2).

Section 483.73(d)(2) will require LTC facilities to participate in a full-scale exercise at least annually. LTC facilities are also required to participate in one additional testing exercise of their choice at least annually. LTC facilities will also have to analyze their responses to, and maintain documentation of all exercises and emergency events. If a LTC facility experienced an actual emergency which required activation of its emergency plan, the LTC facility will be exempt from the requirement for a community or individual, facility-based disaster exercise for 1 year following the onset of the actual event (§ 483.73(d)(2)(ii)).

To comply with these testing requirements, a LTC facility will need to develop a scenario for each exercise. A LTC facility will also need to develop the necessary documentation to record and analyze their response to all testing exercises and emergency events.

Existing requirements for LTC facilities already mandate that these facilities "periodically review the procedures with existing staff, and carry out unannounced staff drills" (§ 483.75(m)(2)). We expect that all LTC facilities are already developing and conducting drills or exercises for their disaster plans. It is also standard practice in the healthcare industry to document what happens during a drill, exercise, or emergency event and analyze the facility's response to those events. However, the LTC facility requirements do not specify how often the facility must conduct a drill or the type of drills. For purposes of determine the burden associated with the testing requirements in this final rule, we will assume that all LTC facilities will need to develop scenarios for their testing exercises and the documentation necessary to record the events during the testing exercises.

To comply with these requirements we expect it will mainly require the involvement of the director of nursing. We expect that the director of nursing will develop the required documentation, as well as the scenarios for the testing exercises. We expect that the administrator will provide some assistance and approve the scenarios.

We estimate that these tasks will require 5 burden hours at a cost of $425. Based on this estimate, it will require 78,495 burden hours (5 burden hours for each LTC facility × 15,699 LTC facilities) for all 15,699 LTC facilities to comply with these requirements at a cost of $6,672,075 ($425 estimated cost for each LTC facility × 15,699 LTC facilities).

TABLE 55—TOTAL COST ESTIMATE FOR A LTC FACILITY TO CONDUCT TRAINING EXERCISES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$85.00	1	$85.00
Director of Nursing	85.00	4	340.00
Totals	....	5	425

TABLE 56—BURDEN HOURS AND COST ESTIMATES FOR ALL 15,699 LTC FACILITIES TO COMPLY WITH THE ICRS CONTAINED IN § 483.73 EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 483.73(a)(1)	0938-New	15,699	15,699	8	125,592	**	10,863,708	10,863,708
§ 483.73(a)(1)–(4)	0938-New	15,699	15,699	12	188,388	**	16,295,562	16,295,562
§ 483.73(b)	0938-New	15,699	15,699	10	156,990	**	13,626,732	13,626,732
§ 483.73(c)	0938-New	15,699	15,699	6	94,194	**	8,006,490	8,006,490
§ 483.73(d)(1)	0938-New	15,699	15,699	10	156,990	**	13,344,150	13,344,150
§ 483.73(d)(2)	0938-New	15,699	15,699	5	78,495	**	6,672,075	6,672,075
Totals	....	15,699	94,194	....	800,649	....	....	68,808,717

**The hourly labor cost is blended between the wages for multiple staffing levels.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 56.

Comment: A commenter appreciated that OBRA '87 provided for a waiver of PRA requirements. However, the commenter requested that we publish the anticipated burden that these requirements would impose on LTC facilities for their information.

Response: We appreciate the commenter's request and have provided a discussion of the anticipated ICRs in this final rule.

K. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 483.475)

Section 483.475(a) will require intermediate care facilities for individuals with intellectual disabilities (ICF/IID) to develop and maintain an emergency preparedness plan that will have to be reviewed and updated at least annually. We proposed that the plan will include the elements set out at § 483.475(a)(1) through (4). We will discuss the burden for these activities individually beginning with the risk assessment.

Section 483.475(a)(1) will require each ICFs/IID to develop a documented, facility-based and community-based risk assessment utilizing an all-hazard approach, including missing clients. We expect an ICF/IID to identify the medical and non-medical emergency events it could experience in the facility and the community in which it is located and determine the likelihood of the facility experiencing an emergency due to the identified hazards. In performing the risk assessment, we expect that an ICF/IID will need to consider its physical location, the geographical area in which it is located, and its client population.

The burden associated with this requirement will be the time and effort necessary to perform a thorough risk assessment. The current CoPs for ICFs/IID already require ICFs/IID to "develop and implement detailed written plans and procedures to meet all potential emergencies and disasters such as fires, severe weather, and missing clients" (42 CFR 483.470(h)(1)). During the process of developing these detailed written plans and procedures, we expect that all ICFs/IID have already performed some type of risk assessment. However, as discussed earlier in the preamble, the current requirement is primarily designed to ensure the health and safety of the ICF/IID clients during emergencies that are within the facility or in the facility's local area. We do not expect that this requirement will be sufficient to protect the health and safety of clients during more widespread local, state, or national emergencies. In addition, an ICF/IID current risk assessment may not address all of the elements required in § 483.475(a). Therefore, all ICFs/IID will have to conduct a thorough review of their current risk assessments, if they have them, and then perform the necessary tasks to ensure that their risk assessments comply with the requirements of this section.

We have not designated any specific process or format for ICFs/IID to use in conducting their risk assessments because we expect ICFs/IID will need maximum flexibility in determining the best way for their facilities to accomplish this task. However, we expect that in the process of developing a risk assessment, an ICF/IID will include representatives from, or obtain input from, all of the major departments in their facilities. Based on our experience with ICFs/IID, we expect that conducting the risk assessment will require the involvement of the ICF/IID administrator and a professional staff person, such as a registered nurse. We expect that both individuals will attend an initial meeting, review relevant sections of the current assessment, develop comments and recommendations for changes to the assessment, attend a follow-up meeting, perform a final review, and approve the risk assessment. We expect that the administrator will coordinate the meetings, perform an initial review of the current risk assessment, critique the risk assessment, offer suggested revisions, coordinate comments, develop the new risk assessment, and assure that the necessary parties approve the new risk assessment. We also expect that the administrator will spend more time reviewing and working on the risk assessment. Thus, we estimate that complying with this requirement will require 8 burden hours to complete at a cost of $657. There are currently 6,237 ICFs/IID. Therefore, it will require an estimated 49,896 burden hours (8 burden hours for each ICF/IID × 6,237 ICFs/IID) for all ICFs/IID to comply with this requirement at a cost of $4,097,709 ($657 estimated cost for each ICF/IID × 6,237 ICFs/IID).

TABLE 57—TOTAL COST ESTIMATE FOR AN ICF/IID TO CONDUCT A RISK ASSESSMENT

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$93	5	$465
Registered Nurse	64	3	192
Total		8	657

Under this final rule, ICFs/IID will be required to develop emergency preparedness plans that addressed the emergency events that could affect not only their facilities but also the communities in which they are located. An ICF/IID current disaster plan might not address all of the medical and non-medical emergency events identified by its risk assessment, include strategies for addressing those emergency events, or address its patient population. It may not specify the type of services the ICF/IID has the ability to provide in an emergency, or continuity of operations, including delegation of authority and succession plans. Thus, we expect that each ICFs/IID will have to review its current plans and compare them to its risk assessments. Each ICF/IID will then need to update, revise, and, in some cases, develop new sections to comply with our requirements.

The burden associated with this requirement will be the resources needed to review, revise, and develop new sections for an existing emergency plan. Based upon our experience with ICFs/IID, we expect that the same individuals who were involved in the risk assessment will be involved in developing the facility's new emergency preparedness plan. We also expect that developing the plan will be more labor intensive and will require more time to complete than the risk assessment. We estimate that it will require 9 burden hours at a cost of $750 for each ICF/IID to develop an emergency plan that complied with the requirements in this section. Based on this estimate, it will require 56,133 burden hours (9 burden hours for each ICF/IID × 6,237 ICFs/IID) to complete the plan at a cost of $4,677,750 ($750 estimated cost for each ICF/IID × 6,237 ICFs/IID).

TABLE 58—TOTAL COST ESTIMATE FOR AN ICF/IID TO DEVELOP AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$93	6	$558
Registered Nurse	64	3	192
Total		9	750

The ICF/IID also will be required to review and update its emergency preparedness plan at least annually. We believe that ICFs/IID already review their emergency preparedness plans periodically. Thus, we believe compliance with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 483.475(b) will require each ICF/IID to develop and implement emergency preparedness policies and procedures, based on its emergency plan set forth in paragraph (a), the risk assessment at paragraph (a)(1), and the communication plan at paragraph (c). We will also require the ICF/IID to review and update these policies and procedures at least annually. At a minimum, the ICF/IID policies and procedures will be required to address the requirements listed at § 483.475(b)(1) through (8).

We expect all ICFs/IID to compare their current emergency preparedness policies and procedures to their emergency preparedness plans, risk assessments, and communication plans. They will then need to revise and, if necessary, develop new policies and procedures to ensure they comply with the requirements in this section.

We expect that all ICFs/II already have some emergency preparedness policies and procedures. As discussed earlier, the current CoPs for ICFs/IID require them to have "written . . . procedures to meet all potential emergencies and disasters" (§ 483.470(h)(1)). In addition, we expect that all ICFs/IID already have procedures that comply with some of the other requirements in this section. For example, as will be discussed later, current regulations require ICFs/IID to perform drills, evaluate the effectiveness of those drills, and take corrective action for any problems they detect (§ 483.470(i)). We expect that all ICFs/IID have developed procedures for safe evacuation from and return to the ICF/IID (§ 483.475(b)(4)) and a process to document and analyze drills and revise their emergency plan when they detect problems.

We expect that each ICF/IID will need to review its current disaster policies and procedures and assess whether they incorporate all of the elements we are proposing. Each ICF/IID also will need to revise, and, if needed, develop new policies and procedures.

The burden incurred by reviewing, revising, updating and, if necessary, developing new emergency policies and procedures will be the resources needed to ensure that the ICF/IID policies and procedures complied with the requirements of this section. We expect that these tasks will involve the ICF/IID administrator and a registered nurse. We estimate that for each ICF/IID to comply will require 9 burden hours at a cost of $750. Based on this estimate, for all 6,237 ICFs/IID to comply with this requirement will require 56,133 burden hours (9 burden hours for each ICF/IID × 6,237 ICFs/IID) at a cost of $4,677,750 ($750 estimated cost for each ICF/IID × 6,237 ICFs/IID).

TABLE 59—TOTAL COST ESTIMATE FOR AN ICF/IID TO DEVELOP POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$93	6	$558
Registered Nurse	64	3	192
Total		9	750

We expect ICFs/IID to review and update their emergency preparedness policies and procedures at least annually. We believe that ICFs/IID already review their policies and procedures periodically. Thus, we believe compliance with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 483.475(c) will require each ICF/IID to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. The ICF/IID will also have to review and update the plan at least annually. The communication plan must include the information set out at § 483.475(c)(1) through (7).

We expect all ICFs/IID to compare their current emergency preparedness communications plans, if they have them, to the requirements in this section. The ICFs/IID also will need to perform any tasks necessary to ensure that they document their communication plans and that those plans comply with the requirements of this section.

We expect that all ICFs/IID have some type of emergency preparedness communication plan. The current CoPs require ICFs/IID to have written disaster plans and procedures for all potential emergencies (§ 483.470(h)(1)). We expect that an integral part of these plans and procedures will include communication. Furthermore, it is standard practice for healthcare organizations to maintain contact information for both staff and outside sources of assistance; have alternate means of communication in case there is an interruption in phone service to the facility (for example, cell phones); and have a method for sharing information and medical documentation with other healthcare providers to ensure continuity of care for their clients. However, many ICFs/IID may not have a formal, written emergency preparedness communication plan, or their plan may not comply with all the elements we are requiring.

The burden associated with complying with this requirement will be the resources required to ensure that the ICF/IID emergency communication plan complied with the requirements. Based upon our experience with ICFs/IID, we anticipate that meeting the requirements in this section will primarily require the involvement of the ICF/IID administrator and a registered nurse. We estimate that for each ICF/IID to comply with the requirement will require 6 burden hours at a cost of $500. Therefore, for all 6,237 ICFs/IID to comply with this requirement will require an estimated 37,442 burden hours (6 burden hours for each ICF/IID × 6,237 ICFs/IID) at a cost of $3,118,500 ($500 estimated cost for each ICF/IID × 6,237 ICFs/IID).

TABLE 60—TOTAL COST ESTIMATE FOR AN ICF/IID TO DEVELOP A COMMUNICATION PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$93	4	$372
Registered Nurse	64	2	128
Total		6	500

The ICFs/IID will also have to review and update their emergency preparedness communication plans at least annually. We believe that ICFs/IID already review their plans, policies, and procedures periodically. Thus, we believe compliance with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 483.475(d) will require ICFs/IID to develop and maintain emergency preparedness training and testing programs that will have to be reviewed and updated at least annually. Each ICF/IID will also have to meet the requirements for evacuation drills and training at § 483.470(i).

To comply with the requirements at § 483.475(d)(1), an ICF/IID will have to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, the ICF/IID will have to provide emergency preparedness training at least annually.

The ICFs/IID will need to compare their current emergency preparedness training programs' contents to their risk assessments and updated emergency preparedness plans, policies and procedures, and communication plans and then revise and, if necessary, develop new sections for their training programs to ensure they complied with the requirements. The current ICFs/IID

CoPs require ICFs/IID to periodically review and provide training to their staff on the facility's emergency plan (§ 483.470(h)(2)). In addition, staff on all shifts must be trained to perform the tasks to which they are assigned for evacuations (§ 483.470(i)(1)(i)). We expect that all ICFs/IID have emergency preparedness training programs for their staff. However, under this final rule, each ICF/IID will need to review its current training program and compare its contents to its updated emergency preparedness plan, policies and procedures, and communications plan. Each ICF/IID also will need to revise and, if necessary, develop new sections for their training program to ensure it complied with the requirements.

The burden will be the time and effort necessary to comply with the requirements. We expect that a registered nurse will be primarily involved in reviewing the ICF/IID current training program and the ICF/IID updated emergency preparedness plan, policies, and procedures, and communication plan; determining what tasks will need to be performed to comply with the requirements of this section; accomplishing those tasks, and developing an updated training program. We expect the administrator will work with the registered nurse to update the training program. We estimate that it will require 7 burden hours for each ICF/IID to develop an emergency training program at a cost of $506. Therefore, it will require an estimated 43,659 burden hours (7 burden hours for each ICF/IID × 6,237 ICFs/IID) to comply with this requirement at a cost of $3,155,922 ($506 estimated cost for each ICF/IID × 6,237 ICFs/IID).

TABLE 61—TOTAL COST ESTIMATE FOR AN ICF/IID TO DEVELOP A TRAINING PROGRAM

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$93	2	$186
Registered Nurse	64	5	320
Total	....	7	506

The ICFs/IID will have to review and update their emergency preparedness training program at least annually. We believe that ICFs/IID already review their emergency preparedness training programs periodically. Thus, we believe compliance with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 483.475(d)(2) will require ICFs/IID to participate in a full-scale exercise and one additional exercise of their choice at least annually. The ICFs/IID will also be required to analyze their responses to and maintain documentation of all testing exercises and emergency events, and revise their emergency plans, as needed. If an ICF/IID experienced an actual natural or man-made emergency that required activation of its emergency plan, the ICF/IID will be exempt from engaging in a full-scale exercise for 1 year following the onset of the actual event. To comply with this requirement, an ICF/IID will need to develop scenarios for each testing exercise. An ICF/IID also will have to develop the required documentation.

The current ICF/IID CoPs require them to hold evacuation drills at least quarterly for each shift and under varied conditions to evaluate the effectiveness of emergency and disaster plans and procedures (§ 483.470(i)(1)). In addition, ICFs/IID must "actually evacuate clients during at least one drill each year on each shift . . . file a report and evaluation on each evacuation drill . . . and investigate all problems with evacuation drills, including accidents, and take corrective action" (42 CFR 483.470(i)(2)). Thus, all 6,450 ICFs/IID already conduct quarterly drills. However, the current CoPs do not indicate the type of drills ICFs/IID must perform. In addition, although the CoPs require that a report and evaluation be filed, this requirement does not ensure that ICFs/IID have developed the type of paperwork we proposed requiring or that scenarios are used for each drill or tabletop exercise. For the purpose of determining a burden for these requirements, all ICFs/IID will have to develop scenarios and all ICFs/IID will have to develop the necessary documentation.

The burden associated with these requirements will be the resources the ICF/IID will need to comply with the requirements. We expect that complying with these requirements will likely require the involvement of a registered nurse. We expect that the registered nurse will develop the required documentation. We also expect that the registered nurse will develop the scenarios for the each testing exercise. We estimate that these tasks will require 4 burden hours at a cost of $256. Based on this estimate, for all 6,237 ICFs/IID to comply, it will require 24,948 burden hours (4 burden hours for each ICF/IID × 6,237 ICFs/IID) at a cost of $1,596,672 ($256 estimated cost for each ICF/IID × 6,237 ICFs/IID).

TABLE 62—TOTAL COST ESTIMATE FOR AN ICF/IID TO CONDUCT TESTING

Position	Hourly wage	Burden hours	Cost estimate
Registered Nurse	$64	4	$256
Total	....	4	256

TABLE 63—BURDEN HOURS AND COST ESTIMATES FOR ALL 6,237 ICFS/IID TO COMPLY WITH THE ICRS CONTAINED IN § 485.475 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 483.475(a)(1)		6,237	6,237	8	49,896	**	4,097,709	4,097,709

TABLE 63—BURDEN HOURS AND COST ESTIMATES FOR ALL 6,237 ICFS/IID TO COMPLY WITH THE ICRS CONTAINED IN § 485.475 CONDITION: EMERGENCY PREPAREDNESS—Continued

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 483.475(a)(1)–(4)		6,237	6,237	9	56,133	**	4,677,750	4,677,750
§ 483.475(b)		6,237	6,237	9	56,133	**	4,677,750	4,677,750
§ 483.475(c)		6,237	6,237	6	37,422	**	3,118,500	3,118,500
§ 483.475(d)(1)		6,237	6,237	7	43,659	**	3,155,922	3,155,922
§ 483.475(d)(2)		6,237	6,237	4	24,948	**	1,596,672	1,596,672
Totals		6,237	37,422	....	268,191	....	....	21,324,303

**The hourly labor cost is blended between the wages for multiple staffing levels.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 63.

L. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 484.22)

Section 484.22(a) will require home health agencies (HHAs) to develop and maintain emergency preparedness plans. Each HHA also will be required to review and update the plan at least annually. Specifically, we proposed that the plan meet the requirements listed at § 484.22(a)(1) through (4). We will discuss the burden for these activities individually, beginning with the risk assessment.

Accreditation may substantially affect the burden a HHA will experience under this final rule. HHAs are accredited by three different accrediting organizations (AOs): The Joint Commission (TJC), The Community Health Accreditation Program (CHAP), and the Accreditation Commission for Health Care, Inc. (ACHC). After reviewing the accreditation standards for all three AOs, neither the standards for CHAP nor the ones for ACHC appeared to ensure substantial compliance with our requirements in this rule. Therefore, the HHAs accredited by CHAP and ACHC will be included with the non-accredited HHAs for the purposed of determining the burden for this final rule.

As of June 2016, there are currently 12,335 HHAs. There are 4,330 TJC-accredited HHAs. A review of TJC deeming standards indicates that the 4,330 TJC-accredited HHAs already perform certain tasks or activities that will partially or completely satisfy our requirements. Therefore, since TJC accreditation is a significant factor in determining the burden, we will analyze the burden for the 4,330 TJC-accredited HHAs separately from the 8,005 non TJC-accredited HHAs (12,335 HHAs–4,330 TJC-accredited HHAs), as appropriate. Note that we obtain data on the number of HHAs, both accredited and non-accredited, from the CMS CASPER data system, which is updated periodically by the individual states. Due to variations in the timeliness of the data submissions, all numbers are approximate, and the number of accredited and non-accredited HHAs may not equal the total number of HHAs.

Section 484.22(a)(1) will require that HHAs develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. To perform this risk assessment, an HHA will need to identify the medical and non-medical emergency events the HHA could experience and how the HHA's essential business functions and ability to provide services could be impacted by those emergency events based on the risks to the facility itself and the community in which it is located. We will expect HHAs to consider the extent of their service area, including the location of any branch offices. An HHA with an existing risk assessment will need to review, revise and update it to comply with our requirements.

For TJC accreditation standards, we used TJC's CAMHC Refreshed Core, January 2008 pages from the Comprehensive Accreditation Manual for Home Care 2008 (CAMHC). In the chapter entitled, "Environmental Safety and Equipment Management" (EC), TJC accreditation standards require HHAs to conduct proactive risk assessments to "evaluate the potential adverse impact of the external environment and the services provided on the security of patients, staff, and other people coming to the organization's facilities" (CAMHC, Standard EC.2.10, EP 3, p. EC–7). These proactive risk assessments should evaluate the risk to the entire organization, and the HHA should conduct one of these assessments whenever it identifies any new external risk factors or begins a new service (CAMHC, Standard EC.2.10, p. EC–7). Moreover, TJC-accredited HHAs are required to develop and maintain "a written emergency management plan describing the process for disaster readiness and emergency management . . ." (CAMHC, Standard EC.4.10, EP 3, p. EC–9). In addition, TJC requires that these plans provide for "processes for managing . . . activities related to care, treatment, and services (for example, scheduling, modifying, or discontinuing services; controlling information about patients; referrals; transporting patients) . . . logistics relating to critical supplies . . . communicating with patient" during an emergency (CAMHC, Standard EC.4.10, EP 10, p. EC–9–10). We expect that any HHA that has conducted a proactive risk assessment and developed an emergency management plan that satisfies the previously described TJC accreditation requirements has already conducted a risk assessment that will satisfy our requirements. Any tasks needed to comply with our requirements will not result in any additional burden. Thus, for the 4,330 TJC-accredited HHAs, the risk assessment requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

It is standard practice for healthcare facilities to prepare for common internal and external medical and non-medical emergencies, based on their location, structure, and the services they provide. We believe that the 8,005 non TJC-accredited HHAs have conducted some type of risk assessment. However, those risk assessments are unlikely to satisfy all of our requirements. Therefore, we will analyze the burden for the 8,005 non TJC-accredited HHAs to comply.

We have not designated any specific process or format for HHAs to use in conducting their risk assessments because we believe that HHAs need the flexibility to determine the best way to accomplish this task. However, we expect that HHAs will include representatives from or input from all of their major departments. Based on our experience working with HHAs, we expect that conducting the risk assessment will require the involvement of an HHA administrator, the director of nursing, director of rehabilitation, and the office manager. We expect that these individuals will attend an initial meeting, review relevant sections of the current assessment, prepare and forward their comments to the administrator and the director of nursing, attend a follow-up meeting, perform a final review, and approve the new risk assessment. We expect that the director of nursing will coordinate the meetings, review the current risk assessment, provide suggestions, coordinate comments, develop the new risk assessment, and ensure that the necessary parties approve it. We expect that the director of nursing will spend more time developing the facility's new risk assessment than the other individuals. We estimate that the risk assessment will require 11 burden hours for each non TJC-accredited HHA to complete at a cost of $959. There are currently about 8,005 non TJC-accredited HHAs. We estimate that for all non TJC-accredited HHAs to comply with this requirement will require 88,055 burden hours (11 burden hours for each non TJC-accredited HHA × 8,005 non TJC-accredited HHAs) at a cost of $7,676,795 ($959 estimated cost for each non TJC-accredited HHA × 8,005 non TJC-accredited HHAs).

TABLE 64—TOTAL COST ESTIMATE FOR A NON TJC-ACCREDITED HHA TO CONDUCT A RISK ASSESSMENT

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	2	$194
Director of Nursing	97	5	485
Director of Rehabilitation	88	2	176
Office Manager	52	2	104
Total		11	959.00

After conducting a risk assessment, HHAs will have to develop an emergency preparedness plan that complied with § 484.22(a)(1) through (4). As discussed earlier, TJC already has accreditation standards similar to the requirements we proposed at § 484.22(a). Thus, we expect that TJC-accredited HHAs have an emergency preparedness plan that will satisfy most of our requirements. Although the current HHA CoPs require that there be a qualified person who "is authorized in writing to act in the absence of the administrator" (§ 484.14(c)), the TJC standards do not specifically address delegations of authority or succession plans. Furthermore, TJC standards do not address persons-at-risk. Therefore, we expect that the 1,815 TJC-accredited HHAs will incur some burden due to reviewing, revising, and in some cases, developing new sections for their emergency preparedness plans. However, we will analyze the burden for TJC-accredited HHAs separately from the 8,005 non TJC-accredited HHAs because we expect the burden for TJC-accredited HHAs to be substantially less.

We expect that the 8,005 non TJC-accredited HHAs already have some type of emergency preparedness plan, as well as delegations of authority and succession plans. However, we also expect that their plans do not comply with all of our requirements. Thus, all non TJC-accredited HHAs will need to review their current plans and compare them to their risk assessments. They also will need to update, revise, and, in some cases, develop new sections for their emergency plans.

Based on our experience with HHAs, we expect that the same individuals who were involved in the risk assessment will be involved in developing the emergency preparedness plan. We estimate that complying with this requirement will require 10 burden hours for each TJC-accredited HHA at a cost of $862. Therefore, for all 4,330 TJC-accredited HHAs to comply will require an estimated 43,300 burden hours (10 burden hours for each TJC-accredited HHA × 4,330 TJC-accredited HHAs) at a cost of $3,732,460 ($862 estimated cost for each HHA × 4,330 TJC-accredited HHAs).

TABLE 65—TOTAL COST ESTIMATE FOR A TJC-ACCREDITED HHA TO DEVELOP AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	2	$194
Director of Nursing	97	4	388
Director of Rehabilitation	88	2	176
Office Manager	52	2	104
Total		10	862

We estimate that complying with this requirement will require 15 burden hours for each of the 8,005 non TJC-accredited HHAs at a cost of $1,293. Therefore, for all 8,005 non TJC-accredited HHAs to comply will require an estimated 120,075 burden hours (15 burden hours for each non TJC-accredited HHA × 8,005 non TJC-accredited HHAs) at a cost of $10,350,465 ($1,293 estimated cost for each non TJC-accredited HHA × 8,005 non TJC-accredited HHAs).

TABLE 66—TOTAL COST ESTIMATE FOR A NON-TJC ACCREDITED HHA TO DEVELOP AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	3	$291
Director of Nursing	97	6	582
Director of Rehabilitation	88	3	264
Office Manager	52	3	156
Total		15	1,293

Based on these estimates, for all 12,335 HHAs to develop an emergency preparedness plan that complies with our requirements will require 163,375 burden hours at a cost of $14,082,925. We will also require HHAs to review and update their emergency preparedness plans at least annually. We believe that HHAs are already reviewing and updating their emergency preparedness plans periodically. Hence, we believe compliance with this requirement will constitute a usual and customary business practice for HHAs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 484.22(b) will require each HHA to develop and implement emergency preparedness policies and procedures based on the emergency plan, risk assessment, communication plan as set forth in § 484.22(a), (a)(1), and (c), respectively. The HHA will also have to review and update its policies and procedures at least annually. We will require that, at a minimum, these policies and procedures address the requirements listed at § 484.22(b)(1) through (6).

We expect that HHAs will review their emergency preparedness policies and procedures and compare them to their risk assessments, emergency preparedness plans, and emergency communication plans. HHAs will need to revise or, in some cases, develop new policies and procedures to ensure they complied with all of the requirements.

In the chapter entitled, "Leadership," TJC accreditation standards require that each HHA's "leaders develop policies and procedures that guide and support patient care, treatment, and services" (CAMHC, Standard LD.3.90, EP 1, p. LD–13). In addition, TJC accreditation standards and EPs specifically require each HHA to develop and maintain an emergency management plan that provides processes for managing activities related to care, treatment, and services, including scheduling, modifying, or discontinuing services (CAMHC, Standard EC.4.10, EP 10, EC–9); identify backup communication systems in the event of failure due to an emergency event (CAMHC, Standard EC.4.10, EP 18, EC–10); and develop processes for critiquing tests of its emergency preparedness plan and modifying the plan in response to those critiques (CAMHC, Standard EC.4.20, EPs 15–17, p. EC–11).

We expect that the 4,330 TJC-accredited HHAs already have emergency preparedness policies and procedures that address some of the requirements at § 484.22(b). However, we do not believe that TJC accreditation requirements ensure that TJC-accredited HHAs' policies and procedures address all of our requirements for emergency policies and procedures. Thus, we will include the 4,330 TJC-accredited HHAs with the 8,005 non TJC-accredited HHAs in our analysis of the burden for § 484.22(b).

Under § 484.22(b)(1), the HHA's individual plans for patients during a natural or man-made disaster will be included as part of the comprehensive patient assessment, which will be conducted according to the provisions at § 484.55. We expect that HHAs already collect data during the comprehensive patient assessment that they will need to develop for each patient's emergency plan. At § 484.22(b)(2), we proposed requiring each HHA to have procedures to inform state and local emergency preparedness officials about HHA patients in need of evacuation from their residences at any time due to an emergency situation based on the patients' medical and psychiatric condition and home environment.

Existing HHA regulations already address § 484.22(b)(1) and (2). For example, regulations at § 484.18 make it clear that HHAs are expected to accept patients only on the basis of a reasonable expectation that they can provide for the patients' medical, nursing, and social needs in the patients' home. Moreover, the plan of care for each patient must cover any safety measures necessary to protect the patient from injury § 484.18(a). Thus, the activities necessary to be in compliance with § 484.22(b)(1) and (2) will constitute usual and customary business practices for HHA and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

We expect that all 12,520 HHAs have some emergency preparedness policies and procedures. However, we also expect that all HHAs will need to review their policies and procedures and revise and, if necessary, develop new policies and procedures that complied with our requirements set out at § 484.22(3) through (6). We expect that a professional staff person, most likely the director of nursing, will review the HHA's policies and procedures and make recommendations for changes or development of additional policies and procedures. The administrator or director of nursing will brief representatives of most of the HHA's major departments and assign staff to make necessary revisions and draft any new policies and procedures. We estimate that complying with this requirement will require 18 burden hours for each HHA at a cost of $1,584. Thus, for all 12,335 HHAs to comply with all of our requirements will require an estimated 222,030 burden hours (18 burden hours for each HHA × 12,335 HHAs) at a cost of $19,538,640 ($1,584 estimated cost for each HHA × 12,335 HHAs).

TABLE 67—TOTAL COST ESTIMATE FOR A HHA TO DEVELOP POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	4	$388
Director of Nursing	97	8	776

TABLE 67—TOTAL COST ESTIMATE FOR A HHA TO DEVELOP POLICIES AND PROCEDURES—Continued

Position	Hourly wage	Burden hours	Cost estimate
Director of Rehabilitation	88	3	264
Office Manager	52	3	156
Total		18	1,584

We are also proposing that HHAs review and update their emergency preparedness policies and procedures at least annually. The current CoPs require HHAs to establish and annually review the agency's policies governing scope of services offered, admission and discharge policies, medical supervision and plans of care, emergency clinical records and program evaluation. (42 CFR 484.16). Thus, we believe that complying with this requirement will constitute a usual and customary business practice for HHAs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

In § 484.22(c), each HHA will be required to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. We proposed that each HHA review and update its communication plan at least annually. We will require that the emergency communication plan include the information listed at § 484.22(c)(1) through (6).

It is standard practice for healthcare facilities to maintain contact information for both staff and outside sources of assistance; alternate means of communication in case there is an interruption in phone service to the facility; and a method of sharing information and medical documentation with other healthcare providers to ensure continuity of care for patients.

All TJC-accredited HHAs are required to identify backup communication systems for both internal and external communication in case of failure due to an emergency (CAMHC, Standard EC.4.10, EP 18, p. EC–10). They are required to have processes for notifying their staff when the HHA initiates its emergency plan (CAMHC, Standard EC.4.10, EP 7, p. EC–9); identifying and assigning staff to ensure that essential functions are covered during emergencies (CAMHC, Standard EC.4.10, EP 9, p. EC–9); and activities related to care, treatment, and services, such as controlling information about their patients (CAMHC, Standard EC.4.10, EP 10, p. EC–9). However, we do not believe these requirements ensure that all TJC-accredited HHAs are already in compliance with our requirements. Thus, we will include the 4,330 TJC-accredited HHAs with the 8,005 non TJC-accredited HHAs in assessing the burden for this requirement.

We expect that all 12,335 HHAs maintain some contact information, an alternate means of communication, and a method for sharing information with other healthcare facilities. However, this will not ensure that all HHAs will be in compliance with our requirements for communication plans. Thus, we will analyze the burden for this requirement for all 12,335 HHAs.

The burden associated with complying with this requirement will be the time and effort necessary for each HHA to review its existing communication plan, if any, and revise it; and, if necessary, to develop new sections for the emergency preparedness communication plan to ensure that it complied with our requirements. Based on our experience with HHAs, we expect that these activities will require the involvement of the HHA's administrator, director of nursing, director of rehabilitation, and office manager. We estimate that complying with this requirement will require 10 burden hours for each HHA at a cost of $826. Thus, for all 12,335 HHAs to comply with these requirements will require an estimated 123,350 burden hours (10 burden hours for each HHA × 123,350 HHAs) at a cost of $10,188,710 ($826 estimated cost for each HHA × 123,350 HHAs).

TABLE 68—TOTAL COST ESTIMATE FOR A HHA TO DEVELOP A COMMUNICATION PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	1	$97
Director of Nursing	97	5	485
Director of Rehabilitation	88.00	1	88
Office Manager	52.00	3	156
Total		10	826

We proposed requiring HHAs to review and update their emergency preparedness communication plans at least annually. We believe that HHAs already review their emergency preparedness plans periodically. Thus, we believe compliance with this requirement will constitute a usual and customary business practice for HHAs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2). Section 484.22(d) will require each HHA to develop and maintain an emergency preparedness training and testing program. Each HHA will also have to review and update its training and testing program at least annually. Section 484.22(d)(1) states that each HHA will have to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, the HHA will have to provide emergency preparedness training at least annually. Each HHA will also have to ensure that their staff could demonstrate knowledge of their emergency procedures.

Based on our experience with HHAs, we expect that all 12,335 HHAs have some type of emergency preparedness training program because this a key component of emergency preparedness and as stated earlier, it is standard practice for healthcare facilities to prepare for common internal and external medical and non-medical emergencies, based on their location, structure, and the services they provide. The 4,330 TJC-accredited HHAs are already required to provide both an initial orientation to their staff before they can provide care, treatment, or services (CAMHC, Standard HR.2.10, EP 2, p. HR–6) and "ongoing in-services, training or other staff activities [that] emphasize job-related aspects of safety . . ." (CAMHC, Standard HR.2.30, EP 4, p. HR–8). Since emergency preparedness is a critical aspect of job-related safety, we expect that TJC-accredited HHAs will ensure that their orientations and ongoing staff training will include the facility's emergency preparedness policies and procedures.

However, we expect that under § 484.22(d), all HHAs will need to compare their training and testing programs with their risk assessments, emergency preparedness plans, emergency policies and procedures, and emergency communication plans. We expect that most HHAs will need to revise and, in some cases, develop new sections for their training programs to ensure that they complied with our requirements. In addition, HHAs will need to provide an orientation and annual training in their facilities' emergency preparedness policies and procedures to individuals providing services under arrangement and volunteers, consistent with their expected roles. Hence, we will analyze the burden of these requirements for all 12,335 HHAs.

Based on our experience with HHAs, we expect that complying with this requirement will require the involvement of an administrator, the director of training, director of nursing, director of rehabilitation, and the office manager. We expect that the director of training will spend more time reviewing, revising or developing new sections for the training program than the other individuals. We estimate that it will require 16 burden hours for each HHA to develop an emergency preparedness training and testing program at a cost of $1,132. Thus, for all 12,335 HHAs to comply will require an estimated 197,360 burden hours (16 burden hours for each HHA × 12,335 HHAs) at a cost of $13,963,220 ($1,132 estimated cost for each HHA × 12,335 HHAs).

TABLE 69—TOTAL COST ESTIMATE FOR A HHA TO DEVELOP A TRAINING PROGRAM

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	2	$194
Director of Nursing	97	2	194
Director of Rehabilitation	88	2	176
Office Manager	52	2	104
Director of Training	58	8	464
Total		16	1,132

We also proposed that HHAs should review and update their emergency preparedness training programs at least annually. The current CoPs require HHAs to establish and annually review the agency's policies governing scope of services offered, admission and discharge policies, medical supervision and plans of care, emergency care clinical records, and program evaluation. We believe that HHAs already review their training and testing programs periodically. Thus, we believe compliance with this requirement will constitute a usual and customary business practice for HHAs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 484.22(d)(2) will require each HHA to conduct exercises to test its emergency plan. Each HHA will have to participate in a full-scale exercise and one additional exercise at least annually. If an HHA experiences an actual natural or man-made emergency that requires activation of the emergency plan, it will be exempt from engaging in a full-scale exercise for 1 year following the onset of the actual event. Each HHA will also be required to analyze its responses to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise its emergency plan as needed. For the purposes of determining the burden for these requirements, we expect that all HHAs will have to comply with all of the requirements. The burden associated with complying with this requirement will be the time and effort necessary to develop the scenarios for the testing exercises and the required documentation. All TJC-accredited HHAs are required to test their emergency management plan once a year; the test cannot be a tabletop exercise (CAMHC, Standard EC.4.20, EP 1 and Note 1, p. EC–11). The TJC also requires HHAs to critique the drills and modify their emergency management plans in response to those critiques (CAMHC, Standard EC.4.20, EPs 15–17, p. EC–11). Therefore, TJC-accredited HHAs already prepare scenarios for drills, develop documentation to record the events during drills, critique them, and modify their emergency preparedness plans in response. However, TJC standards do not describe what type of drill HHAs must conduct or require a tabletop exercise annually. Thus, TJC accreditation standards will not ensure that TJC-accredited HHAs will be in compliance with our requirements. Therefore, we will include the 4,330 TJC-accredited HHAs with the 8,005 non TJC-accredited HHAs in our analysis of the burden for these requirements.

Based on our experience with HHAs, we expect that the same individuals who are responsible for developing the HHA's training and testing program will develop the scenarios for the testing exercises and the accompanying documentation. We expect that the director of nursing will spend more time on these activities than will the other individuals. We estimate that it will require 7 burden hours for each HHA to comply with the requirements at an estimated cost of $586. Thus, for all 12,335 HHAs to comply with the requirements in this section will require an estimated 86,345 burden hours (7 burden hours for each HHA × 12,335 HHAs) at a cost of $7,228,310 ($586 estimated cost for each HHA × 12,335 HHAs).

TABLE 70—TOTAL COST ESTIMATE FOR A HHA TO CONDUCT TESTING

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	1	$97
Director of Nursing	97	3	291
Director of Rehabilitation	88	1	88
Office Manager	52	1	52
Director of Training	58	1	58
Total	....	7	586

TABLE 71—BURDEN HOURS AND COST ESTIMATES FOR ALL 12,335 HHAS TO COMPLY WITH THE ICRS CONTAINED IN § 484.22 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 484.22(a)(1)	0938–New	8,005	8,005	11	88,055	**	7,676,795	7,676,795
§ 484.22(a)(1)–(4) (TJC-accredited)	0938–New	4,330	4,330	10	43,300	**	3,732,460	3,732,460
§ 484.22(a)(1)–(4) (Non TJC-accredited)	0938–New	8,005	8,005	15	120,075	**	10,350,465	10,350,465
§ 484.22(b)	0938–New	12,335	12,335	18	222,030	**	19,538,640	19,538,640
§ 484.22(c)	0938–New	12,335	12,335	10	123,350	**	10,188,710	10,188,710
§ 484.22(d)(1)	0938–New	12,335	12,335	16	197,360	**	13,963,220	13,963,220
§ 484.22(d)(2)	0938–New	12,335	12,335	8	86,345	**	7,228,310	7,228,310
Total	....	24,670	69,680	....	880,515	....	....	72,678,600

** The hourly labor cost is blended between the wages for multiple staffing levels.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 71.

M. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 485.68)

Section 485.68(a) will require all Comprehensive Outpatient Rehabilitation Facilities (CORFs) to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. We proposed that the plan meet the requirements listed at § 485.68(a)(1) through (5).

Section 485.68(a)(1) will require a CORF to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. The CORFs will need to identify the medical and non-medical emergency events they could experience. The current CoPs for CORFs already require CORFs to have "written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters" (§ 485.64). We expect that all CORFs have performed some type of risk assessment during the process of developing their disaster policies and procedures. However, their risk assessments may not meet our requirements. Therefore, we expect that all CORFs will need to review their existing risk assessments and perform the tasks necessary to ensure that those assessments meet our requirements.

We have not designated any specific process or format for CORFs to use in conducting their risk assessments because we believe they need the flexibility to determine how best to accomplish this task. However, we expect that CORFs will obtain input from all of their major departments. Based on our experience with CORFs, we expect that conducting the risk assessment will require the involvement of the CORF's administrator and a therapist. The type of therapists at each CORF varies, depending upon the services offered by the facility. For the purposes of determining the burden, we will assume that the therapist is a physical therapist. We expect that both the administrator and the therapist will attend an initial meeting, review relevant sections of the current assessment, develop comments and recommendations for changes, attend a follow-up meeting, perform a final review, and approve the new risk assessment. We expect that the administrator will coordinate the meetings, review and critique the risk assessment, coordinate comments, develop the new risk assessment, and ensure that it was approved.

We estimate that complying with this requirement will require 8 burden hours at a cost of $722. There are currently 205 CORFs. Therefore, it will require an estimated 1,640 burden hours (8 burden hours for each CORF × 205 CORFs) for all CORFs to comply at a cost of $148,010 ($722 estimated cost for each CORF × 205 CORFs).

TABLE 72—TOTAL COST ESTIMATE FOR A CORF TO CONDUCT A RISK ASSESSMENT

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	5	$485
Physical Therapist	79	3	237
Total	....	8	722

After conducting the risk assessment, each CORF will need to review, revise, and, if necessary, develop new sections for its emergency plan so that it complied with our requirements. The current CoPs for CORFs require them to have a written disaster plan (§ 485.64) that must be developed and maintained with the assistance of appropriate experts and address, among other things, procedures concerning the transfer of casualties and records, notification of outside emergency personnel, and evacuation routes (§ 485.64(a)). Thus, we expect that all CORFs have some type of emergency preparedness plan. However, we also expect that all CORFs will need to review, revise, and develop new sections for their plans to ensure that their plans complied with all of our requirements.

Based on our experience with CORFs, we expect that the administrator and physical therapist who were involved in developing the risk assessment will be involved in developing the emergency preparedness plan. However, we expect that it will require more time to complete the emergency plan than to complete the risk assessment. We estimate that complying with this requirement will require 11burden hours at a cost of $1,013 for each CORF. Therefore, it will require an estimated 2,255 burden hours (11 burden hours for each CORF × 205 CORFs) for all CORFs to complete an emergency preparedness plan at a cost of $207,665 ($1,013 estimated cost for each CORF × 205 CORFs).

TABLE 73—TOTAL COST ESTIMATE FOR A CORF TO DEVELOP AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	8	$776
Physical Therapist	79	3	237
Total		11	1,013

The CORF also will be required to review and update its emergency preparedness plan at least annually. We believe that CORFs already review their plans periodically. Therefore, compliance with the requirement for an annual review of the emergency preparedness plan will constitute a usual and customary business practice for CORFs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 485.68(b) will require CORFs to develop and implement emergency preparedness policies and procedures based on their emergency plans, risk assessments, and communication plans as set forth in § 485.68(a), (a)(1), and (c), respectively. We will also require CORFs to review and update these policies and procedures at least annually. We will require that a CORF's policies and procedures address, at a minimum, the requirements listed at § 485.68(b)(1) through (4).

We expect that all CORFs have some emergency preparedness policies and procedures. As discussed earlier, the current CoPs for CORFs already require CORFs to have "written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters" (42 CFR 485.64). However, all CORFs will need to review their policies and procedures and compare them to their risk assessments, emergency preparedness plans, and communication plans. Most CORFs will need to revise their existing policies and procedures or develop new policies and procedures to ensure they complied with all of our requirements.

We expect that both the administrator and the therapist will attend an initial meeting, review relevant policies and procedures, make recommendations for changes, attend a follow-up meeting, perform a final review, and approve the policies and procedures. We expect that the administrator will coordinate the meetings, coordinate the comments, and ensure that they are approved.

We estimate that it will take 9 burden hours for each CORF to comply with this requirement at a cost of $819. Therefore, it will take all 205 CORFs 1,845 burden hours (9 burden hours for each CORF × 205 CORFs = 1,845 burden hours) to comply with this requirement at a cost of $167,895 ($819 estimated cost for each CORF × 205 CORFs).

TABLE 74—TOTAL COST ESTIMATE FOR A CORF TO DEVELOP POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	6	$582
Physical Therapist	79	3	237
Total		9	819

Section 485.68(b) also proposes that CORFs review and update their emergency preparedness policies and procedures at least annually. We believe that CORFs already review their policies and procedures periodically. Therefore, we believe that complying with this requirement will constitute a usual and customary business practice for CORFs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 485.68(c) will require CORFs to develop and maintain emergency preparedness communication plans that complied with both federal and state law and that will be reviewed and updated at least annually. We proposed that a CORF's communication plan include the information listed in § 485.68(c)(1) through (5). Current CoPs require CORFs to have a written disaster plan that must include, among other things, "procedures for notifying community emergency personnel" (§ 486.64(a)(2)). In addition, it is standard practice in the healthcare industry to maintain contact information for staff and outside sources of assistance; alternate means of communication in case there is an interruption in phone service to the facility; and a method for sharing information and medical documentation with other healthcare providers to ensure continuity of care for their patients. However, many CORFs may not have formal, written emergency preparedness communication plans. Therefore, we expect that all CORFs will need to review, update, and in some cases, develop new sections for their plans to ensure they complied with all of our requirements.

Based on our experience with CORFs, we anticipate that satisfying the requirements in this section will primarily require the involvement of the CORF's administrator with the assistance of a physical therapist to review, revise, and, if needed, develop new sections for the CORF's emergency preparedness communication plan. We estimate that it will take 8 burden hours for each CORF to comply with this requirement at a cost of $722. Therefore, it will take 1,640 burden hours (8 burden hours for each CORF × 205 CORFs) for all CORFs to comply at a cost of $148,010 ($722 estimated cost for each CORF × 205 CORFs).

TABLE 75—TOTAL COST ESTIMATE FOR A CORF TO DEVELOP A COMMUNICATION PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	5	$485
Physical Therapist	79	3	237
Total		8	722

We proposed that each CORF will also have to review and update its emergency preparedness communication plan at least annually. We believe that compliance with this requirement will constitute a usual and customary business practice for CORFs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 485.68(d) will require CORFs to develop and maintain an emergency preparedness training and testing program that must be reviewed and updated at least annually. We proposed that each CORF will have to satisfy the requirements listed at § 485.68(d)(1) and (2).

Section 485.68(d)(1) will require that each CORF provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, each CORF will have to provide emergency preparedness training at least annually. Each CORF will also have to ensure that its staff could demonstrate knowledge of its emergency procedures. All new personnel will have to be oriented and assigned specific responsibilities regarding the CORF's emergency plan within two weeks of their first workday. In addition, the training program will have to include instruction in the location and use of alarm systems and signals and firefighting equipment.

The current CORF CoPs at § 485.64 require CORFs to ensure that all personnel are knowledgeable, trained, and assigned specific responsibilities regarding the facility's disaster procedures. Section 485.64(b)(1) specifies that CORFs must also provide ongoing training and drills for all personnel associated with the facility in all aspects of disaster preparedness. In addition, § 485.64(b)(2) specifies that all new personnel must be oriented and assigned specific responsibilities regarding the facility's disaster plan within 2 weeks of their first workday.

In evaluating the requirement for § 485.68(d)(1), we expect that all CORFs have an emergency preparedness training program for new employees, as well as ongoing training for all staff. However, under this final rule, all CORFs will need to compare their current training programs to their risk assessments, emergency preparedness plans, policies and procedures, and communication plans. CORFs will then need to revise, and in some cases, develop new material for their training programs.

We expect that these tasks will require the involvement of an administrator and a physical therapist. We expect that the administrator will review the CORF's current training program to identify necessary changes and additions to the program. We expect that the physical therapist will work with the administrator to develop the revised and updated training program. We estimate it will require 8 burden hours for each CORF to develop an emergency training program at a cost of $722. Therefore, for all CORFs to comply will require an estimated 1,640 burden hours (8 burden hours for each CORF × 205 CORFs) at a cost of $148,010 ($722 estimated cost for each CORF × 205 CORFs).

TABLE 76—TOTAL COST ESTIMATE FOR A CORF TO CONDUCT TRAINING

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	5	$485
Physical Therapist	79	3	237
Total		8	722

We also proposed that each CORF review and update its emergency preparedness training program at least annually. We believe that CORFs already review their training programs periodically. Thus, we believe complying with the requirement for an annual review of the emergency preparedness training program will constitute a usual and customary business practice for CORFs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 485.68(d)(2) will require CORFs to participate in a full-scale exercise and a paper-based, tabletop exercise at least annually. If a full-scale exercise was not available, the CORF will have to conduct a full-scale exercise at least annually. If a CORF experienced an actual natural or man-made emergency that required activation of its emergency plan, it will be exempt from engaging in a full-scale exercise for 1 year following the onset of the actual event. CORFs will also be required to analyze their responses to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise their emergency plans, as needed. To comply with this requirement, a CORF will need to develop scenarios for these drills and exercises. The current CoPs at § 485.64(b)(1) require CORFs to provide ongoing training and drills for all personnel associated with the facility in all aspects of disaster preparedness.'' However, the current CoPs do not specify the type of drill, how often the CORF must conduct drills, or that a CORF must use scenarios for their drills and tabletop exercises.

Based on our experience with CORFs, we expect that the same individuals who develop the emergency preparedness training program will develop the scenarios for the drills and exercises, as well as the accompanying documentation. We expect that the administrator will spend more time on these tasks than the physical therapist. We estimate that for each CORF to comply with the requirements will require 6 burden hours at a cost of $546. Therefore, for all 205 CORFs to comply will require an estimated 1,230 burden hours (6 burden hours for each CORF × 205 CORFs) at a cost of $111,930 ($528 estimated cost for each CORF × 221 CORFs).

Based on the previous analysis, for all 205 CORFs to comply with the ICRs contained in this final rule will require 10,250 total burden hours at a total cost of $931,520.

TABLE 77—TOTAL COST ESTIMATE FOR A CORF TO CONDUCT TESTING

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	4	$388
Physical Therapist	79	2	158
Total	....	6	546

TABLE 78—BURDEN HOURS AND COST ESTIMATES FOR ALL 205 CORFS TO COMPLY WITH THE ICRS CONTAINED IN § 485.68 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 485.68(a)(1)	0938—New	205	205	8	1,640	**	148,010	148,010
§ 485.68(a)(2)–(4)	0938—New	205	205	11	2,255	**	207,665	207,665
§ 485.68(b)	0938—New	205	205	9	1,845	**	167,895	167,895
§ 485.68(c)	0938—New	205	205	8	1,640	**	148,010	148,010
§ 485.68(d)(1)	0938—New	205	205	8	1,640	**	148,010	148,010
§ 485.68(d)(2)	0938—New	205	205	6	1,230	**	111,930	111,930
Totals	....	205	1,230	....	10,250	....	....	931,520

** The hourly labor cost is blended between the wages for multiple staffing levels.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 78.

N. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 485.625)

Section 485.625(a) will require critical access hospitals (CAHs) to develop and maintain a comprehensive emergency preparedness program that utilizes an all-hazards approach and will have to be reviewed and updated at least annually. Each CAH's emergency plan will have to include the elements listed at § 485.625(a)(1) through (4).

Section 485.625(a)(1) will require each CAH to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. CAHs will need to review their existing risk assessments and perform any tasks necessary to ensure that it complied with our requirements.

As of June 2016, there are approximately 1,337 CAHs. CAHs with distinct part units were included in the hospital burden analysis. Approximately 445 CAHs are accredited either by TJC (338), DNV GL (76), or by the AOA/HFAP (31); the remainder are non-accredited CAHs.

Many of the TJC and AOA/HFAP accreditation standards for CAHs are similar to the requirements in this final rule. For purposes of determining the burden, we have analyzed the burden for the 338 TJC-accredited and 31 AOA/HFAP-accredited CAHs separately from the non-accredited CAHs. DNV GL's accreditation standards do not meet the requirements for emergency preparedness of this final rule and as a result, we have included the DNV GL-accredited CAHs with the non-accredited CAHs in our burden analysis. Note that we obtained data on the number of CAHs, both accredited and non-accredited, from the CMS CASPER database, which is updated periodically by the individual states. Due to variations in the timeliness of the data submissions, all numbers are approximate, and the number of accredited and non-accredited CAHs may not equal the total number of CAHs.

For purposes of determining the burden for TJC-accredited CAHs, we used TJC's Comprehensive Accreditation Manual for Critical Access Hospitals: The Official Handbook 2008 (CAMCAH). In the chapter entitled, ''Management of the Environment of Care'' (EC), Standard EC.4.11 requires CAHs to plan for managing the consequences of emergency events (CAMCAH, Standard EC.4.11, CAMCAH Refreshed Care, January 2008, pp. EC–10–EC–11). CAHs are required to perform a hazard vulnerability analysis (HVA), which requires each CAH to, among other things, ''identify events that could affect demand for its services or its ability to provide those services, the likelihood of those events occurring, and the consequences of those events'' (Standard EC.4.11, EP 2, p. EC–10a). The HVA ''should identify potential hazards, threats, and adverse events, and assess their impact on the care, treatment, and services [the CAH] must sustain during an emergency,'' and the HVA ''is designed to assist [CAHs] in gaining a realistic understanding of their vulnerabilities, and to help focus their resources and planning efforts''

(CAMCAH, Emergency Management, Introduction, p. EC–10). Thus, we expect that TJC-accredited CAHs already conduct a risk assessment that will comply with the requirements we proposed. Thus, for the 338 TJC-accredited CAHs, the risk assessment requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

For purposes of determining the burden for AOA/HFAP-accredited CAHs, we used the AOA/HFAP's Healthcare Facilities Accreditation Program: Accreditation Requirements for Critical Access CAHs 2007 (ARCAH). In Chapter 11 entitled, "Physical Environment," CAHs are required to have disaster plans, external disaster plans that include triaging victims, and weapons of mass destruction response plans (ARCAH, Standards 11.07.01, 11.07.02, and 11.07.05–6, pp. 11–38 through 11–41, respectively). In addition, AOA/HFAP-accredited CAHs must "coordinate with federal, state, and local emergency preparedness and health authorities to identify likely risks for their area . . . and to develop appropriate responses" (ARCAH, Standard 11.02.02, p. 11–5). Thus, we believe that to develop their plans, AOA/HFAP-accredited CAHs already perform some type of risk assessment. However, the AOA/HFAP standards do not require a documented facility-based and community-based risk assessment, as we proposed. Therefore, we will include the 31 AOA/HFAP-accredited CAHs with non-accredited CAHs in determining the burden for our risk assessment requirement.

The CAH CoPs currently require CAHs to assure the safety of their patients in nonmedical emergencies (§ 485.623) and to take appropriate measures that are consistent with the particular conditions in the area in which the CAH is located (§ 485.623(c)(4)). To satisfy this requirement in the CoPs, we expect that CAHs have already conducted some type of risk assessment. However, that requirement does not ensure that CAHs have conducted a documented, facility-based, and community-based risk assessment that will satisfy our requirements.

We believe that under this final rule, the 999 non TJC-accredited CAHs (1,337 CAHs − 338 TJC-accredited CAHs) will need to review, revise, and, in some cases, develop new sections for their current risk assessments to ensure compliance with all of our requirements.

We have not designated any specific process or format for CAHs to use in conducting their risk assessments because we believe that CAHs need the flexibility to determine the best way to accomplish this task. However, we expect that CAHs will include representatives from or obtain input from all of their major departments in the process of developing their risk assessments.

Based on our experience with CAHs, we expect that these activities will require the involvement of a CAH's administrator, medical director, director of nursing, facilities director, and food services director. We expect that these individuals will attend an initial meeting, review relevant sections of the current risk assessment, provide comments, attend a follow-up meeting, perform a final review, and approve the new or updated risk assessment. We expect the administrator will coordinate the meetings, perform an initial review of the current risk assessment, coordinate comments, develop the new risk assessment, and ensure that the necessary parties approved it.

We estimate that the risk assessment requirement for non TJC-accredited CAHs will require 15 burden hours to complete at a cost of $1,495. We estimate that for the 999 non TJC-accredited CAHs to comply with the risk assessment requirement will require 14,985 burden hours (15 burden hours for each CAH × 999 non TJC-accredited CAHs) at a cost of $1,493,505 ($1,495 estimated cost for each non TJC-accredited CAH × 999 non TJC-accredited CAHs).

TABLE 79—TOTAL COST ESTIMATE FOR A NON-TJC ACCREDITED CAH TO CONDUCT A RISK ASSESSMENT

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	5	$485
Medical Director	181	2	362
Director of Nursing	97	3	291
Facility Director	83	3	249
Food Services Director	54	2	108
Total	....	15	1,495

After conducting the risk assessment, CAHs will have to develop and maintain emergency preparedness plans that comply with § 485.625(a)(1) through (4). We will expect all CAHs to compare their emergency plans to their risk assessments and then revise and, if necessary, develop new sections for their emergency plans to ensure that they complied with our requirements.

TJC-accredited CAHs must develop and maintain an Emergency Operations Plan (EOP) (CAMCAH Standard EC.4.12, p. EC–10a). The EOP must cover the management of six critical areas during emergencies: Communications, resources and assets, safety and security, staff roles and responsibilities, utilities, and patient clinical and support activities (CAMCAH, Standards EC.4.12 through 4.18, pp. EC–10a–EC–10g). In addition, as discussed earlier, TJC-accredited CAHs also are required to conduct an HVA (CAMCAH, Standard EC.4.11, EP 2, p. EC–10a). Therefore, we expect that the 338 TJC-accredited CAHs already have emergency preparedness plans that will satisfy our requirements. If a CAH needed to complete additional tasks to comply with the requirement, the burden will be negligible. Thus, for the 338 TJC-accredited CAHs, this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

The AOA/HFAP-accredited CAHs must work with federal, state, and local emergency preparedness authorities to identify the likely risks for their location and geographical area and develop appropriate responses to assure the safety of their patients (ARCAH, Standard 11.02.02, p. 11–5). Among the elements that AOA/HFAP-accredited CAHs must specifically consider are the special needs of their patient population, availability of medical and non-medical supplies, both internal and external communications, and the transfer of patients to home or other healthcare settings (ARCAH, Standard

11.02.02, p. 11–5). In addition, there are requirements for disaster and disaster response plans (ARCAH, Standards 11.07.01, 11.07.02, and 11.07.06, pp. 11–38 through 11–40). There also are specific requirements for plans for responses to weapons of mass destruction, including chemical, nuclear, and biological weapons; communicable diseases, and chemical exposures (ARCAH, Standards 11.07.02 and 11.07.05–11.07.06, pp. 11–39 through 11–41). However, the AOA/HFAP accreditation requirements require only that CAHs assess their most likely risks (ARCAH, Standard 11-02.02, p. 11–5), and we are proposing that CAHs be required to conduct a risk assessment utilizing an all-hazards approach. Thus, we expect that AOA/HFAP-accredited CAHs will have to compare their risk assessments they conducted in accordance with § 485.625(a)(1) to their current plans and then revise, and in some cases develop new sections for, their plans. Therefore, we will assess the burden for these 31 AOA/HFAP-accredited CAHs with the non-accredited CAHs.

The CAH CoPs require all CAHs to ensure the safety of their patients during non-medical emergencies (§ 485.623). They are also required to provide, among other things, for evacuation of patients, cooperation with disaster authorities, emergency power and lighting in their emergency rooms and for flashlights and battery lamps in other areas, an emergency water and fuel supply, and any other appropriate measures that are consistent with their particular location (§ 485.623). Thus, we believe that all CAHs have developed some type of emergency preparedness plan. However, we also expect that the 999 non-accredited CAHs will have to review their current plans and compare them to their risk assessments and revise and, in some cases, develop new sections for their current plans to ensure that their plans will satisfy our requirements.

Based on our experience with CAHs, we expect that the same individuals who were involved in conducting the risk assessment will be involved in developing the emergency preparedness plan. We expect that these individuals will attend an initial meeting, review relevant sections of the current emergency preparedness plan(s), prepare and send their comments to the administrator, attend a follow-up meeting, perform a final review, and approve the new plan. We expect that the administrator will coordinate the meetings, perform an initial review, coordinate comments, revise the plan, and ensure that the necessary parties approve the new plan. We estimate that complying with this requirement will require 26 burden hours at a cost of $2,561. Therefore, we estimate that for all 999 non TJC-accredited CAHs to comply with this requirement will require 25,974 burden hours (26 burden hours for each non TJC-accredited CAH × 999 non TJC-accredited CAHs) at a cost of $2,558,439 ($2,561 estimated cost for each non TJC-accredited CAH × 999 non TJC-accredited CAHs).

TABLE 80—TOTAL COST ESTIMATE FOR A NON-TJC ACCREDITED CAH TO DEVELOP AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	8	$776
Medical Director	181	3	543
Director of Nursing	97	6	582
Facility Director	83	6	498
Food Services Director	54	3	162
Total	....	26	2,561.00

Under this final rule, CAHs also will be required to review and update their emergency preparedness plans at least annually. The CAH CoPs already require CAHs to perform a periodic evaluation of their total program at least once a year (§ 485.641(a)(1)). Hence, all CAHs should already have an individual or team that is responsible that is for the periodic review of their total program. Therefore, we believe that this requirement will constitute a usual and customary business practice for CAHs and will not be subject to the PRA in accordance with the implementing regulations of the PRA 5 CFR 1320.3(b)(2).

Under § 485.625(b), we will require CAHs to develop and maintain emergency preparedness policies and procedures based on their emergency plans, risk assessments, and communication plans as set forth in § 485.625(a), (a)(1), and (c), respectively. We will also require CAHs to review and update these policies and procedures at least annually. These policies and procedures will have to address, at a minimum, the requirements listed at § 485.625(b)(1) through (8).

We expect that all CAHs will review their policies and procedures and compare them to their risk assessments, emergency preparedness plans, and emergency communication plans. The CAHs will need to revise, and, in some cases, develop new policies and procedures to incorporate all of the provisions previously noted and address all of our requirements.

The CAMCAH chapter entitled, "Leadership" (LD), requires TJC-accredited CAH leaders to "develop policies and procedures that guide and support patient care, treatment, and services" (CAMCAH, Standard LC.3.90, EP 1, CAMCAH Refreshed Core, January 2008, p. LD–11). Thus, we expect that TJC-accredited CAHs already have some policies and procedures for the activities and processes required for accreditation, including their EOP. As discussed later, many of the required elements we proposed have a corresponding requirement in the CAH TJC accreditation standards.

We proposed at § 485.625(b)(1) that CAHs have policies and procedures that address the provision of subsistence needs for staff and patients, whether they evacuate or shelter in place. TJC-accredited CAHs must make plans for obtaining and replenishing medical and non-medical supplies, including food, water, and fuel for generators and transportation vehicles (CAMCAH, Standard EC.4.14, EPs 1–4, p. EC–10d). In addition, they must identify alternative means of providing electricity, water, fuel, and other essential utility needs in cases where their usual supply is disrupted or compromised (CAMCAH, Standard EC.4.17, EPs 1–5, p. EC–10f). We expect that TJC-accredited CAHs that comply with these requirements will be in compliance with our requirement concerning subsistence needs at § 485.625(b)(1).

We are proposing at § 485.625(b)(2) that CAHs have policies and procedures for a system to track the location of on-duty staff and sheltered patients in the CAH's care during an emergency. TJC-accredited CAHs must plan for communicating with their staff, as well as patients and their families, at the beginning of and during an emergency (CAMCAH, Standard EC.4.13, EPs 1, 2, and 5, p. EC–10c). We expect that TJC-accredited CAHs that comply with these requirements will be in compliance with our requirement.

Section 485.625(b)(3) will require CAHs to have a plan for the safe evacuation from the CAH. TJC-accredited CAHs are required to make plans to evacuate patients as part of managing their clinical activities (CAMCAH, Standard EC.4.18, EP 1, p. EC–10g). They also must plan for the evacuation and transport of patients, their information, medications, supplies, and equipment to alternative care sites (ACSs) when the CAH cannot provide care, treatment, and services in its facility (CAMCAH, Standard EC.4.14, EPs 9–11, p. EC–10d). We expect that TJC-accredited CAHs that comply with these requirements will be in compliance with our requirement.

We proposed at § 485.625(b)(4) that CAHs have policies and procedures for a means to shelter in place for patients, staff, and volunteers who remain in the facility. The rationale for CAMCAH Standard EC.4.18 states, "[a] catastrophic emergency may result in the decision to keep all patients on the premises in the interest of safety" (CAMCAH, Standard EC.4.18, p. EC–10f). Therefore, we expect that TJC-accredited CAHs will be substantially in compliance with our requirement.

Section 485.625(b)(5) will require CAHs to have policies and procedures that address a system of medical documentation that preserves patient information, protects the confidentiality of patient information, and ensures that records are secure and readily available. The CAMCAH chapter entitled "Management of Information" (IM), requires TJC-accredited CAHs to have storage and retrieval systems for their clinical/service and CAH-specific information (CAMCAH, Standard IM.3.10, EP 5, CAMCAH Refreshed Core, January 2008, p. IM–11), as well as to ensure the continuity of their critical information for patient care, treatment, and services (CAMCAH, Standard IM.2.30, CAMCAH Refreshed Core, January 2008, p. IM–9). They also must ensure the privacy and confidentiality of patient information (CAMCAH, Standard IM.2.10, CAMCAH Refreshed Core, January 2008, p. IM–7). In addition, TJC-accredited CAHs must have plans for transporting patients and their clinical information, including transferring information to ACSs (CAMCAH Standard EC.4.14, EP 10 and 11, p. EC–10d and Standard EC.4.18, EP 6, pp. EC–10g, respectively). Therefore, we expect that TJC-accredited CAHs will be substantially in compliance with § 485.625(b)(5).

Section 485.625(b)(6) will require CAHs to have policies and procedures that addressed the use of volunteers in an emergency or other emergency staffing strategies. TJC-accredited CAHs must define staff roles and responsibilities in their EOP and ensure that they train their staff for their assigned roles (CAMCAH, Standard EC.4.16, EPs 1 and 2, p. EC–10e). Also, the rationale for Standard EC.4.15 indicates that the CAH "determines the type of access and movement to be allowed by . . . emergency volunteers . . . when emergency measures are initiated" (CAMCAH, Standard EC.4.15, Rationale, p. EC–10d). In addition, in the chapter entitled "Medical Staff" (MS), CAHs "may grant disaster privileges to volunteers that are eligible to be licensed independent practitioners" (CAMCAH, Standard MS.4.110, CAMCAH Refreshed Care, January 2008, p. MS–20). Finally, in the chapter entitled "Management of Human Resources" (HR), CAHs "may assign disaster responsibilities to volunteer practitioners" (CAMCAH, Standard HR.1.25, CAMCAH Refreshed Core, January 2008, p. HR–6). Although the TJC accreditation requirements address some of our requirements, we do not believe TJC-accredited CAHs will be in compliance with all requirements in § 485.625(b)(6).

Based upon the previous discussion, we expect that the activities required for compliance by TJC-accredited CAHs with § 485.625(b)(1) through (5) constitutes usual and customary business practices for PRAs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

However, we do not believe TJC-accredited CAHs will be substantially in compliance with § 485.625(b)(6) through (8). We will discuss the burden for TJC-accredited CAHs to comply with these requirements later in this section.

The AOA/HFAP accreditation standards also contain requirements for policies and procedures related to safety and disaster preparedness. The AOA/HFAP-accredited CAHs are required to maintain plans and performance standards for disaster preparedness (ARCAH, Standard 11.00.02 Required Plans and Performance Standards, p. 11–2). They also must have "written procedures for possible situations to be followed by each department and service within the CAH and for each building used for patient treatment or housing" (ARCAH, Standard 11.07.01 Disaster Plans, Explanation, p. 11–38). AOA/HFAP-accredited CAHs also are required to have a safety team or committee that is responsible for all issues related to safety within the CAH (ARCAH, Standard 11.02.03, p. 11–7). The individuals or team will be responsible for all policies and procedures related to safety in the CAH (ARCAH, Standard 11.02.03, Explanation, p. 11–7). We expect that these performance standards and procedures are similar to some of our requirements for policies and procedures.

In regard to § 485.625(b)(1), AOA/HFAP-accredited CAHs are required to consider "pharmaceuticals, food, other supplies and equipment that may be needed during emergency/disaster situations" and "provisions if gas, water, electricity supply is shut off to the community" when they are developing their emergency plans (ARCAH, Standard 11.02.02 Building Safety, Elements 5 and 11, pp. 11–5 and 11–6, respectively). In addition, CAHs are required "to provide emergency gas and water as needed to provide care to inpatients and other persons who may come to the CAH in need of care" (ARCAH, Standard 11.03.22 Emergency Gas and Water, p. 11–22 through 11–23). However, these standards do not specifically address all of the requirements in this section.

In regard to § 485.625(b)(2), AOA/HFAP-accredited CAHs are required to consider how they will communicate with their staff within the CAH when developing their emergency plans (ARCAH, Standard 11.02.02 Building Safety, Element 7, p. 11–6). They also are required to have a "call tree" in their external disaster plan that must be updated at least annually (ARCAH, Standard 11.07.04 Staff Call Tree, p. 11–40). However, these requirements do not sufficiently cover the requirements to track the location of staff and patients during and after an emergency.

In regard to § 485.625(b)(3), which requires policies and procedures regarding the safe evacuation from the facility, AOA/HFAP-accredited CAHs are required to consider the "transfer or discharge of patients to home, other healthcare settings, or other CAHs" and the "transfer of patients with CAH equipment to another CAH or healthcare setting" (ARCAH, Standard 11.02.02 Building Safety, Elements 12 and 13, p. 11–6). AOA/HFAP-accredited CAHs also are required to consider in their emergency plans how to maintain communication with external entities should their telephones and computers either cease to operate or become overloaded (ARCAH, Standard 11.02.02, Element 6, p. 11–6). AOA/HFAP-accredited CAHs must also "develop and implement a comprehensive plan to ensure that the safety and well-being of patients are assured during emergency situations" (ARCAH, Standard 11.02.02 Building Safety, pp. 11–4 through 11–7). However, we do not believe these requirements are detailed enough to ensure that AOA/HFAP-accredited CAHs are compliant with our requirements.

In regard to § 485.625(b)(4), AOA/HFAP-accredited CAHs are required to consider the special needs of their patient population and the security of those patients and others that come to them for care when they develop their emergency plans (ARCAH, Standard 11.02.02 Building Safety, Elements 2 and 3, p. 11–5). In addition, as described earlier, they also must consider the food, pharmaceuticals, and other supplies and equipment they may need during an emergency in developing their emergency plan (ARCAH, Standard 11.02.02, Element 5, p. 11–5). However, these requirements do not specifically mention volunteers and CAHs are required only to consider these elements in developing their plans.

Therefore, we believe that AOA/HFAP-accredited CAHs have likely already incorporated many of the elements necessary to satisfy the requirements in § 485.625(b); however, they will need to thoroughly review their current policies and procedures and perform whatever tasks are necessary to ensure that they complied with all of our requirements for emergency policies and procedures. Because we expect that AOA/HFAP-accredited CAHs already comply with many of our requirements, we will include the AOA/HFAP-accredited CAHs with the TJC-accredited CAHs in determining the burden.

The burden for the 31 AOA/HFAP-accredited CAHs and the 338 TJC-accredited CAHs to comply with all of the requirements in § 485.625(b) will be the resources required to develop written policies and procedures that comply with all of our requirements for emergency policies and procedures. Based on our experience working with CAHs, we expect that accomplishing these activities will require the involvement of an administrator, the medical director, director of nursing, facilities director, and food services director. We expect that the administrator will review the policies and procedures and make recommendations for necessary changes or additional policies or procedures. The CAH administrator will brief other staff and assign staff to make necessary revisions or draft new policies and procedures and disseminate them to the appropriate parties. We estimate that complying with this requirement will require 10 burden hours for each TJC and AOA/HFAP-accredited CAH at a cost of $983. For all 369 TJC and AOA/HFAP-accredited CAHs to comply with these requirements will require an estimated 3,690 burden hours (10 burden hours for each TJC or AOA/HFAP-accredited CAH × 369 TJC and AOA/HFAP-accredited CAHs) at a cost of $362,727 ($983 estimated cost for each TJC or AOA/HFAP-accredited CAH × 369 TJC and AOA/HFAP-accredited CAHs).

TABLE 81—TOTAL COST ESTIMATE FOR AN ACCREDITED CAH TO DEVELOP POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	4	$388
Medical Director	181	1	181
Director of Nursing	97	2	194
Facility Director	83	2	166
Food Services Director	54	1	54
Total		10	983.00

We expect that the 892 non-accredited CAHs already have developed some emergency preparedness policies and procedures. The current CAH CoPs require CAHs to develop, maintain, and review policies to ensure quality care and a safe environment for their patients (§§ 485.627(a), 485.635(a), and 485.641(a)(1)(iii)). In addition, certain activities associated with our requirements are addressed in the current CAH CoPs. For example, all CAHs are required to have agreements or arrangements with one or more providers or suppliers, as appropriate, to provide services to their patients (§ 485.635(c)).

The burden associated with the development of emergency policies and procedures will be the resources needed to review, revise, and if needed, develop emergency preparedness policies and procedures that include our requirements. We believe the individuals and tasks will be the same as described earlier for the TJC and AOA/HFAP-accredited CAHs. However, the non-accredited CAHs will require more time to accomplish these activities. We estimate that a non-accredited CAH's compliance will require 14 burden hours at a cost of $1,357. For all 892 unaccredited CAHs to comply with this requirement will require an estimated 12,488 burden hours (14 burden hours for each non-accredited CAHs × 892 non-accredited CAHs) at a cost of $1,210,444 ($1,357 estimated cost for each non-accredited CAH × 892 non-accredited CAHs).

TABLE 82—TOTAL COST ESTIMATE FOR A NON-ACCREDITED CAH TO DEVELOP POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	6	$582
Medical Director	181	1	181
Director of Nursing	97	3	291
Facility Director	83	3	249
Food Services Director	54	1	54

TABLE 82—TOTAL COST ESTIMATE FOR A NON-ACCREDITED CAH TO DEVELOP POLICIES AND PROCEDURES—Continued

Position	Hourly wage	Burden hours	Cost estimate
Total		14	1,357

Section 485.625(b) will also require CAHs to review and update their emergency preparedness policies and procedures at least annually. As discussed earlier, TJC and AOA/HFAP-accredited CAHs already periodically review their policies and procedures. In addition, the existing CAH CoPs require periodic reviews of the CAH's healthcare policies (§§ 485.627(a), 485.635(a), and 485.641(a)(1)(iii)). Thus, we believe compliance with this requirement will constitute a usual and customary business practice for all CAHs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 485.625(c) will require CAHs to develop and maintain emergency preparedness communication plans that complied with both federal and state law. We proposed that CAHs review and update these plans at least annually. We proposed that these communication plans include the information listed at § 485.625(c)(1) through (7).

We expect that all CAHs will review their emergency preparedness communication plans and compare them to their risk assessments and emergency plans. We also expect that CAHs will revise and, if necessary, develop new sections that will comply with our requirements. Based on our experience with CAHs, they have some type of emergency preparedness communication plan. Furthermore, it is standard practice for healthcare facilities to maintain contact information for both staff and outside sources of assistance; alternate means of communications in case there is an interruption in phone service to the facility; and a method for sharing information and medical documentation with other healthcare providers to ensure continuity of care for their patients. Thus, we believe that most, if not all, CAHs are already in compliance with § 485.625(c)(1) through (3).

However, all CAHs will need to review and, if needed, revise and update their plans to ensure compliance with § 485.625(c)(4) through (7). The TJC-accredited CAHs are required to establish strategies or plans for emergency communications (CAMCAH, Standard 4.13, p. EC–10b–10c). These plans must cover both internal and external communications and include back-up technologies and communication systems (CAMCAH, Standard 4.13, and EPs 1–14, p. EC–10b–EC–10c). However, we do not believe that these standards will ensure compliance with § 485.625(c)(4) through (7). Thus, we will include the 338 TJC-accredited CAHs in the burden of this final rule.

The AOA/HFAP-accredited CAHs must develop and implement communication plans to ensure the safety of their patients during emergencies (AOA/HFAP Standard 11.02.02). These plans must specifically include both internal and external communications (AOA/HFAP Standard 11.02.02, Elements 6, 7, and 10). Based on these standards, we do not believe they ensure compliance with § 485.625(c)(4) through (7). Thus, we will include these 31 AOA/HFAP-accredited CAHs in the burden of this final rule.

The burden associated with complying with this requirement will be the resources required to develop a communication plan that complied with the requirements of this section. Based on our experience with CAHs, we expect that accomplishing these activities will require the involvement of an administrator, director of nursing, and the facilities director. We expect that the administrator will review the communication plan and make recommendations for necessary changes or additions. The director of nursing and the facilities director will meet with the administrator to discuss and revise or draft new sections for the CAH's existing emergency communication plan. We estimate that complying with this requirement will require 9 burden hours for each CAH at a cost of $831. We estimate that for all 1,337 CAHs to comply with the requirements for an emergency preparedness communication plan will require 12,033 burden hours (9 burden hours for each CAH × 1,337 CAHs) at a cost of $1,111,047 ($831 estimated cost for each CAH × 1,337 CAHs).

TABLE 83—TOTAL COST ESTIMATE FOR A CAH TO DEVELOP A COMMUNICATION PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	3	$291
Director of Nursing	97	3	291
Facility Director	83	3	249
Total		9	831

Section 485.625(c) also will require CAHs to review and update their emergency preparedness communication plans at least annually. All CAHs are required to evaluate their entire program at least annually (§ 485.641(a)). Therefore, we believe compliance with this requirement will constitute a usual and customary business practice for CAHs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 485.625(d) will require CAHs to develop and maintain emergency preparedness training and testing programs. We will also require CAHs to review and update their training and testing programs at least annually. We proposed that a CAH comply with the requirements listed at § 485.625(d)(1) and (2).

Regarding § 485.625(d)(1), CAHs will have to provide initial training in emergency preparedness policies and procedures, including prompt reporting and extinguishing fires, protection, and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with firefighting and disaster authorities, to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, the CAH will have to provide emergency preparedness training at least annually.

We expect that all CAHs will review their current training programs and compare them to their risk assessments and emergency preparedness plans, emergency policies and procedures, and emergency communication plans. The CAHs will need to revise and, if necessary, develop new sections or materials to ensure their training and testing programs complied with our requirements.

Current CoPs require CAHs to train their staffs on how to handle emergencies (§ 485.623(c)(1)). However, this training primarily addresses internal emergencies, such as a fire inside the facility. In addition, both TJC and AOA/HFAP require CAHs to provide their staff with training. TJC-accredited CAHs are required to provide their staff with both an initial orientation and on-going training (CAMCAH, Standards HR.2.10 and 2.30, pp. HR–8 and HR—9, respectively). On-going training must also be documented (CAMCAH, Standard HR.2.30, EP 8, p. HR–10). The AOA/HFAP-accredited CAHs are required to provide an education program for their staff and physicians for the CAH's emergency response preparedness (AOA/HFAP Standard 11.07.01). Each CAH also must provide an education program specifically for the CAH's response plan for weapons of mass destruction (AOA Standard 11.07.07).

Thus, we expect that all CAHs provide some emergency preparedness training for their staff. However, neither the current CoPs nor the TJC and AOA/HFAP accreditation standards ensure compliance with all our requirements. All CAHs will need to review their risk assessments, emergency preparedness plans, policies and procedures, and communication plans and then revise or, in some cases, develop new sections for their training programs to ensure compliance with our requirements. They also will need to revise, update, or, in some cases, develop new materials for the initial and ongoing training.

Based on our experience with CAHs, we expect that complying with our requirement will require the involvement of an administrator, the director of nursing, and the facilities director. We expect that the director of nursing will perform the initial review of the training program, brief the administrator and the director of facilities, and revise or develop new sections for the training program, based on the group's decisions. We estimate that each CAH will require 14 burden hours to develop an emergency preparedness training program at a cost of $1,316. Therefore, for all 1,337 CAHs to comply with this requirement will require an estimated 18,718 burden hours (14 burden hours for each CAH × 1,337 CAHs) at a cost of $1,759,492 ($1,316 estimated cost for each CAH × 1,337 CAHs).

TABLE 84—TOTAL COST ESTIMATE FOR A CAH TO CONDUCT TRAINING

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	2	$194
Director of Nursing	97	9	873
Facility Director	83	3	249
Total	....	14	1,316

Section 485.625(d)(1) also will require CAHs to review and update their emergency preparedness training programs at least annually. Existing regulations require all CAHs to evaluate their entire program at least annually (§ 485.641(a)). Therefore, we believe compliance with this requirement will constitute a usual and customary business practice for CAHs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

The CAHs also will be required to maintain documentation of their training. Based on our experience with CAHs, it is standard practice for them to document the training they provide to staff and other individuals. If a CAH needed to make any changes to their normal business practices to comply with this requirement, the burden will be negligible. Thus, we believe compliance with this requirement will constitute a usual and customary business practice for CAHs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 485.625(d)(2) will require CAHs to participate in a full-scale exercise and a paper-based, tabletop exercise at least annually. If a full-scale exercise was not available, the CAH will have to conduct a full-scale exercise at least annually. CAHs also will be required to analyze the CAH's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CAH's emergency plan, as needed. If a CAH experienced an actual natural or man-made emergency that required activation of the emergency plan, it will be exempt from the requirement for a full-scale exercise for 1 year following the onset of the emergency (§ 485.625(d)(2)(ii)). Thus, to meet these requirements, CAHs will need to develop scenarios for each drill and exercise and develop the required documentation.

If a CAH participated in a full-scale exercise, it will likely not need to develop the scenario for that drill. However, for the purpose of determining the burden, we will assume that CAHs need to develop scenarios for both the testing exercises annually.

The TJC-accredited CAHs are required to test their EOP twice a year, either as a planned exercise or in response to an emergency (CAMCAH, Standard EC.4.20, EP 1, p. EC–12). These tests must be monitored, documented, and analyzed (CAMCAH, Standard EC.4.20, EPs 8–19, pp. EC–12–EC–13). Thus, we believe that TJC-accredited CAHs already develop scenarios for these tests. We also expect that they also have developed the documentation necessary to record and analyze their tests and responses to actual emergency events. Therefore, we believe compliance with this requirement will constitute a usual and customary business practice for TJC-accredited CAHs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

The AOA/HFAP-accredited CAHs are required to conduct two disaster drills annually (AOA/HFAP Standard 11.07.03). In addition, AOA/HFAP-accredited CAHs are required to participate in weapons of mass destruction drills, as appropriate (AOA/HFAP Standard 11.07.09). We expect that since AOA/HFAP-accredited CAHs already conduct disaster drills, they also develop scenarios for the drills. In addition, it is standard practice in the healthcare industry to document and analyze tests that a facility conducts. Thus, we believe compliance with this requirement will constitute a usual and customary business practice for AOA/HFAP-accredited CAHs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Based on our experience with CAHs, we expect that the 892 non-accredited CAHs already have some type of emergency preparedness training program and conduct some type of drills or exercises to test their emergency preparedness plans. However, this does not ensure that most CAHs already perform the activities needed to comply with our requirements. Thus, we will analyze the burden for these requirements for the 892 non-accredited CAHs.

The 892 non-accredited CAHs will be required to develop scenarios for testing exercises and the documentation necessary to record and later analyze the events that occurred during these tests and actual emergency events. Based on our experience with CAHs, we believe that the same individuals who developed the emergency preparedness training program will develop the scenarios for the tests and the accompanying documentation. We expect that the director of nursing will spend more time than will the other individuals developing the scenarios and the accompanying documentation. We estimate that it will require 8 burden hours for the 892 non-accredited CAHs to comply with these requirements at a cost of $762. Therefore, for all 892 non-accredited CAHs to comply with these requirements will require an estimated 7,136 burden hours (8 burden hours for each non-accredited CAH × 892 non-accredited CAHs) at a cost of $679,704 ($762 estimated cost for each non-accredited CAH × 892 non-accredited CAHs).

TABLE 85—TOTAL COST ESTIMATE FOR A NON-ACCREDITED CAH TO CONDUCT TESTING

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	1	$97
Director of Nursing	97	6	582
Facility Director	83	1	83
Total	....	8	762

TABLE 86—BURDEN HOURS AND COST ESTIMATES FOR ALL 1,337 CAHS TO COMPLY WITH THE ICRS CONTAINED IN § 485.625 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 485.625(a)(1)	0938–New	999	999	15	14,985	**	1,493,505	1,493,505
§ 485.625(a)(2)–(4)	0938–New	999	999	26	25,974	**	2,558,439	2,558,439
§ 485.625(b) (TJC and AOA/HFAP-Accredited)	0938–New	369	369	10	3,690	**	362,727	362,727
§ 485.625(b) (Non-accredited)	0938–New	892	892	14	12,488	**	1,210,444	1,210,444
§ 485.625(c)	0938–New	1,337	1,337	9	12,033	**	1,111,047	1,111,047
§ 485.625(d)(1)	0938–New	1,337	1,337	14	18,718	**	1,759,492	1,759,492
§ 485.625(d)(2)	0938–New	892	892	8	7,136	**	679,704	679,704
Total	....	3,597	6,825	....	95,024	....	....	9,175,358

** The hourly labor cost is blended between the wages for multiple staffing levels.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 86.

O. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 485.727)

Section 485.727(a) will require clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services (organizations) to develop and maintain emergency preparedness plans and review and update the plan at least annually. We are proposing that the plan comply with the requirements listed at § 485.727(a)(1) through (6).

Section 485.727(a)(1) will require organizations to develop documented, facility-based and community-based risk assessment utilizing an all-hazards approach. Organizations will need to identify the medical and non-medical emergency events they could experience both at their facilities and in the surrounding area.

The current CoPs for Organizations require these providers to have "a written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster" (§ 485.727(a)). To comply with this CoP, we expect that all of these providers have already performed some type of risk assessment during the process of developing their disaster plans and policies and procedures. However, these providers will need to review their current risk assessments and make any revisions to ensure they complied with our requirements.

We have not designated any specific process or format for these providers to use in conducting their risk assessments because we believe that they need the flexibility to determine the best way to accomplish this task. Providers of physical therapy and speech therapy services should include input from all of their major departments in the process of developing their risk assessments. Based on our experience with these providers, we expect that conducting the risk assessment will require the involvement of the organization's administrator and a therapist. The types of therapists at each Organization vary depending upon the services offered by the facility. For the purposes of determining the PRA burden, we will assume that the therapist is a physical therapist. We expect that both the administrator and the therapist will attend an initial meeting, review the current assessment, develop comments and recommendations for changes to the assessment, attend a follow-up meeting, perform a final review, and approve the new risk assessment. We expect that the administrator will coordinate the meetings, review and critique the current risk assessment initially, offer suggested revisions, coordinate comments, develop the new risk assessment, and ensure that the necessary parties approve it. We also expect that the administrator will spend more time reviewing and working on the risk assessment than the physical therapist. We estimate that complying with this requirement will require 9 burden hours at a cost of $901. We estimate that it will require 19,215 burden hours (9 burden hours for each organization × 2,135 organizations) for all organizations to comply with this requirement at a cost of $1,710,135 ($901 estimated cost for each organization × 2,135 organizations).

TABLE 87—TOTAL ESTIMATED COST FOR AN ORGANIZATION TO CONDUCT A RISK ASSESSMENT

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$94	6	$564
Physical Therapist	79	3	237
Total	....	9	801

After conducting the risk assessment, each organization will need to develop and maintain an emergency preparedness plan and review and update it at least annually. Current CoPs require these providers to have a written disaster plan with accompanying procedures for fires, explosions, and other disasters (§ 485.727(a)). The plan must include or address the transfer of casualties and records, the location and use of alarm systems and signals, methods of containing fire, notification of appropriate persons, and evacuation routes and procedures (§ 485.727(a)). Thus, we expect that all of these organizations have some type of emergency preparedness plan and that these plans address many of our requirements. However, all organizations will need to review their current plans and compare them to their risk assessments. Each organization will need to revise, update, and, in some cases, develop new sections to complete a comprehensive emergency preparedness plan that complied with our requirements.

Based on our experience with these organizations, we expect that the administrator and physical therapist who were involved in developing the risk assessment will be involved in developing the emergency preparedness plan. However, we expect it will require more time to complete the plan and that the administrator will be the most heavily involved in reviewing and developing the organization's emergency preparedness plan. We estimate that for each organization to comply will require 12 burden hours at a cost of $1,083. We estimate that it will require 25,620 burden hours (12 burden hours for each organization × 2,135 organizations) to complete the plan at a cost of $2,312,205 ($1,083 estimated cost for each organization × 2,135 organizations).

TABLE 88—TOTAL ESTIMATED COST FOR AN ORGANIZATION TO DEVELOP AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$94	9	$846
Physical Therapist	79	3	237
Total	....	12	1,083

Each organization will also be required to review and update its emergency preparedness plan at least annually. We believe that these organizations already review their plans periodically. Thus, we believe complying with this requirement will constitute a usual and customary business practice for organizations and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 485.727(b) will require organizations to develop and implement emergency preparedness policies and procedures based on their risk assessments, emergency plans, communication plans as set forth in § 485.727(a)(1), (a), and (c), respectively. It will also require organizations to review and update these policies and procedures at least annually. At a minimum, we will require that an organization's policies and procedures address the requirements listed at § 485.727(b)(1) through (4).

We expect that all organizations have emergency preparedness policies and procedures. As discussed earlier, the current CoPs require organizations to have procedures within their written disaster plan to be followed for fires, explosions, or other disasters (§ 485.727(a)). In addition, we expect that those procedures already address some of the specific elements required in this section. For example, the current requirements at § 485.727(a)(1) through (4) are similar to our requirements at § 485.727(a)(1) through (5). However, all organizations will need to review their policies and procedures, assess whether their policies and procedures incorporate all of the necessary elements of their emergency preparedness program, and, if necessary, take the appropriate steps to ensure that their policies and procedures are in compliance with our requirements.

We expect that the administrator and the physical therapist will be primarily involved with reviewing and revising the current policies and procedures and, if needed, developing new policies and procedures. We estimate that it will require 10 burden hours for each organization to comply at a cost of $895. We estimate that for all organizations to comply will require 21,350 burden hours (10 burden hours for each organization × 2,135 organizations) at a cost of $1,910,825 ($895 estimated cost for each organization × 2,135 organizations).

TABLE 89—TOTAL ESTIMATED COST FOR AN ORGANIZATION TO DEVELOP POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$94	7	$658
Physical Therapist	79	3	237
Total		10	895

We will require organizations to review and update their emergency preparedness policies and procedures at least annually. We believe that these providers already review their emergency preparedness policies and procedures periodically. Therefore, we believe compliance with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 485.727(c) will require organizations to develop and maintain emergency preparedness communication plans that complied with both federal and state law and will be reviewed and updated at least annually. The communication plan will have to include the information listed at § 485.727(c)(1) through (5).

We expect that all organizations have some type of emergency preparedness communication plan. Current CoPs for these organizations already require them to have a written disaster plan with procedures that must include, among other things, "notification of appropriate persons" (§ 485.727(a)(4)). Thus, we expect that each organization has the contact information they will need to comply with this requirement. In addition, it is standard practice for healthcare facilities to maintain contact information for both staff and outside sources of assistance; alternate means of communications in case there is an interruption in phone service to the facility; and a method for sharing information and medical documentation with other healthcare providers to ensure continuity of care for their patients. However, many organizations may not have formal, written emergency preparedness communication plans or their plans may not be fully compliant with our requirements. Therefore, we expect that all organizations will need to review, update, and, in some cases, develop new sections for their plans.

Based on our experience with these organizations, we anticipate that satisfying the requirements in this section will primarily require the involvement of the organization's administrator with the assistance of a physical therapist. We estimate that for each organization to comply will require 8 burden hours at a cost of $722. We estimate that for all 2,135 organizations to comply will require 17,080 burden hours (8 burden hours for each organizations × 2,135 organizations) at a cost of $1,541,470 ($722 estimated cost for each organization × 2,135 organizations).

TABLE 90—TOTAL ESTIMATED COST FOR AN ORGANIZATION TO DEVELOP A COMMUNICATION PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$94	6	$564
Physical Therapist	79	2	158
Total		8	722

We are proposing that organizations must review and update their emergency preparedness communication plans at least annually. We believe that these organizations already review their emergency communication plans periodically. Thus, we believe compliance with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 485.727(d) will require organizations to develop and maintain emergency preparedness training and testing programs and review and update these programs at least annually. Specifically, we are proposing that organizations comply with the requirements listed at § 485.727(d)(1) and (2).

According to § 485.727(d)(1), organizations will have to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, the CAH will have to provide emergency preparedness training at least annually.

Current CoPs require organizations to ensure that "all employees are trained, as part of their employment orientation, in all aspects of preparedness for any disaster. The disaster program includes orientation and ongoing training and drills for all personnel in all procedures in case of a disaster (42 CFR 485.727(b)). Thus, we expect that organizations already have an emergency preparedness training program for new employees, as well as ongoing training for all staff. However, organizations will need to review their current training programs and compare them to their risk assessments and emergency preparedness plans, policies and procedures, and communication plans. Organizations will need to review, revise, and, in some cases, develop new material for their training programs so that they comply with our requirements.

We expect that complying with this requirement will require the involvement of an administrator and a physical therapist. We expect that the administrator will primarily be involved in reviewing the organization's current training program and the current emergency preparedness program; determining what tasks will need to be performed and what materials will need to be developed to comply with our requirements; and developing the materials for the training program. We expect that the physical therapist will work with the administrator to develop the revised and updated training program. We estimate that it will require 8 burden hours for each organization to develop a comprehensive emergency training program at a cost of $722. Therefore, it will require an estimated 17,080 burden hours (8 burden hours for each organization × 2,135 organizations) to comply with this requirement at a cost of $1,541,470 ($722 estimated cost for each organization × 2,135 organizations).

TABLE 91—TOTAL ESTIMATED COST FOR AN ORGANIZATION TO CONDUCT TRAINING

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$94	6	$564
Physical Therapist	79	2	158
Total		8	722

In § 485.727(d)(1), we also proposed requiring that an organization must review and update its emergency preparedness training program at least annually. We believe that these providers already review their emergency preparedness training programs periodically. Thus, we believe compliance with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 485.727(d)(2) will require organizations to participate in a full-scale exercise at least annually. They will also be required to conduct one additional exercise of their choice at least annually. If an organization experienced an actual natural or man-made emergency that required activation of its emergency plan, it will be exempt from engaging in a drill for 1 year following the onset of the actual event. Organizations also will be required to analyze their response to and maintain documentation of all the testing exercises and emergency events, and revise their emergency plan, as needed. To comply with this requirement, an organization will need to develop scenarios for their drills and exercises. An organization also will have to develop the documentation necessary for recording and analyzing their responses to the testing exercises and actual emergency events.

The current CoPs require organizations to have a written disaster plan that is periodically rehearsed and have ongoing drills (§ 485.727(a) and (b)). Thus, we expect that all 2,135 organizations currently conduct some type of drill or exercise of their disaster plan. However, the current organizations CoPs do not specify the type of drill, how they are to conduct the drills, or whether the drills should be community-based. In addition, there is no requirement for a paper-based, tabletop exercise. Thus, these requirements do not ensure that organizations will be in compliance with our requirements. Therefore, we will analyze the burden from these requirements for all organizations.

The 2,135 organizations will be required to develop scenarios for testing exercises and the necessary documentation. Based on our experience with organizations, we expect that the same individuals who develop the emergency preparedness training program will develop the scenarios for the drills and exercises and the accompanying documentation. We expect that the administrator will spend more time than the physical therapist developing the scenarios and the documentation. We estimate that for each organization to comply will require 3 burden hours at a cost of $267. Based on that estimate, it will require 6,405 burden hours (3 burden hours for each organization x 2,135 organizations) at a cost of $570,045 ($267 estimated cost for each organization x 2,135 organizations).

TABLE 92—TOTAL ESTIMATED COST FOR AN ORGANIZATION TO CONDUCT TESTING

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$90	2	$188
Physical Therapist	76	1	79
Total		3	267

TABLE 93—BURDEN HOURS AND COST ESTIMATES FOR ALL 2,135 ORGANIZATIONS TO COMPLY WITH THE ICRS CONTAINED IN § 485.727 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 485.727(a)(1)	0938–New	2,135	2,135	9	19,215	**	1,710,135	1,710,135
§ 485.727(a)(2)–(4)	0938–New	2,135	2,135	12	25,620	**	2,312,205	2,312,205
§ 485.727(b)	0938–New	2,135	2,135	10	21,350	**	1,910,825	1,910,825
§ 485.727(c)	0938–New	2,135	2,135	8	17,080	**	1,541,470	1,541,470
§ 485.727(d)(1)	0938–New	2,135	2,135	8	17,080	**	1,541,470	1,541,470
§ 485.727(d)(2)	0938–New	2,135	2,135	3	6,405	**	570,045	570,045
Totals		2,135	12,8100		106,750			9,586,150

** The hourly labor cost is blended between the wages for multiple staffing levels.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 93.

P. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 485.920)

Section 485.920(a) will require Community Mental Health Centers (CMHCs) to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. Specifically, we proposed that the plan must meet the requirements listed at § 485.920(a)(1) through (4).

We expect all CMHCs to identify the likely medical and non-medical emergency events they could experience within the facility and the community in which it is located and determine the likelihood of the facility experiencing an emergency due to the identified hazards. We expect that in performing the risk assessment, a CMHC will need to consider its physical location, the geographical area in which it is located and its patient population.

The burden associated with this requirement will be the time and effort necessary to perform a thorough risk assessment. We expect that most, if not all, CMHCs have already performed at least some of the work needed for a risk assessment because it is standard practice for healthcare organizations to prepare for common emergencies, such as fires, interruptions in communication and power, and storms. However, many CMHCs may not have performed a risk assessment that complies with the requirements. Therefore, we expect that most, if not all, CMHCs will have to perform a thorough review of their current risk assessment and perform the tasks necessary to ensure that the facility's risk assessment complies with the requirements.

We have not designated any specific process or format for CMHCs to use in conducting their risk assessments because we believe CMHCs need maximum flexibility in determining the best way for their facilities to accomplish this task. However, we expect that in the process of developing a risk assessment, healthcare organizations will include representatives from or obtain input from all major departments. Based on our experience with CMHCs, we expect that conducting the risk assessment will require the involvement of the CMHC administrator, a psychiatric registered nurse, and a clinical social worker or mental health counselor. We expect that most of these individuals will attend an initial meeting, review relevant sections of the current assessment, prepare and forward their comments to the administrator, attend a follow-up meeting, perform a final review, and approve the risk assessment. We expect that the administrator will coordinate the meetings, do an initial review of the current risk assessment, critique the risk assessment, offer suggested revisions, coordinate comments, develop the new risk assessment, and assure that the necessary parties approve the new risk assessment. It is likely that the CMHC administrator will spend more time reviewing and working on the risk assessment than the other individuals. We estimate that complying with the requirement to conduct a risk assessment will require 10 burden hours for a cost of $788. There are currently 198 CMHCs. Therefore, it will require an estimated 1,980 burden hours (10 burden hours for each CMHC x 198 CMHCs) for all CMHCs to comply with this requirement at a cost of $156,024 ($788 estimated cost for each CMHC × 198 CMHCs).

TABLE 94—TOTAL COST ESTIMATE FOR A CMHC TO CONDUCT A RISK ASSESSMENT

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$94	6	$564
Psychiatric Registered Nurse	71	2	142
Social Worker	41	2	82
Total	....	10	788

After conducting the risk assessment, CMHCs will need to develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. CMHCs will need to compare their current emergency plan, if they have one, to their risk assessment. They will then need to revise and, if necessary, develop new sections of their plan to ensure it complies with the requirements.

It is standard practice for healthcare organizations to make plans for common disasters they may confront, such as fires, interruptions in communication and power, and storms. Thus, we expect that all CMHCs have some type of emergency preparedness plan. However, their plan may not address all likely medical and non-medical emergency events identified by the risk assessment. Furthermore, their plans may not include strategies for addressing likely emergency events or address their patient population, the type of services they have the ability to provide in an emergency, or continuity of operation, including delegations of authority and succession plans. We expect that CMHCs will have to review their current plan and compare it to their risk assessment, as well as to the other requirements in § 485.920(a). We expect that most CMHCs will need to update and revise their existing emergency plan and, in some cases, develop new sections to comply with our requirements.

The burden associated with this requirement will be due to the resources needed to develop an emergency preparedness plan or to review, revise, and develop new sections for an existing emergency plan. Based upon our experience with CMHCs, we expect that the same individuals who were involved in the risk assessment will be involved in developing the emergency preparedness plan. We also expect that developing the plan will require more time to complete than the risk assessment. We expect that the administrator and a psychiatric nurse will spend more time reviewing and developing the CMHC's emergency preparedness plan. We expect that the clinical social worker or mental health counselor will review the plan and provide comments on it to the administrator. We estimate that it will require 15 burden hours for a CMHC to develop its emergency plan at a cost of $1,113. Based on this estimate, it will require 2,970 burden hours (15 burden hours for each CMHC × 198 CMHCs) for all CMHCs to complete their plans at a cost of $220,374 ($1,113 estimated cost for each CMHC × 198 CMHCs).

TABLE 95—TOTAL COST ESTIMATE FOR A CMHC TO DEVELOP AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$94	6	$564
Psychiatric Registered Nurse	71	6	426
Social Worker	41	3	123
Total	....	15	220,374

The CMHC will be required to review and update its emergency preparedness plan at least annually. For the purpose of determining the burden for this requirement, we expect that the CMHCs will review and update their plans annually.

We expect that all CMHCs have an administrator that is responsible for the day-to-day operation of the CMHC. This will include ensuring that all of the CMHC's plans are up-to-date and comply with the relevant federal, state, and local laws, regulations, and ordinances. In addition, it is standard practice in the healthcare industry for facilities to have professional staff persons who periodically review their plans and procedures. However, the current CMHC CoPs do not include a requirement for an emergency preparedness plan and as such, there is no requirement for an annual review of the plan. Therefore, we will analyze the burden from this requirement for all CMHCs.

Based on our experience with CMHCs, we expect that the same individuals who develop the emergency preparedness plan will annually review and update the plan. We expect that the administrator and registered nurse will spend more time than the social worker on the review of the plan and documentation of the plan updates. We estimate that for each CMHC to comply will require 5 burden hours at a cost of $371. Based on that estimate, it will require 990 burden hours (5 burden hours for each organization × 198 organizations) at a cost of $73,458 ($371 estimated cost for each organization × 198 organizations).

TABLE 96—TOTAL ESTIMATED COST FOR A CMHC TO REVIEW AND UPDATE AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$94	2	$188
Registered Nurse	71	2	142
Social Worker	41	1	41
Total	....	5	371.00

Section 485.920(b) will require CMHCs to develop and maintain emergency preparedness policies and procedures based on the emergency plan, the communication plan, and the risk assessment. We also proposed requiring CMHCs to review and update these policies and procedures at least annually. The CMHC's policies and procedures will be required to address, at a minimum, the requirements listed at § 485.920(b)(1) through (7).

We expect that all CMHCs will compare their current emergency preparedness policies and procedures to their emergency preparedness plan, communication plan, and their training and testing program. They will need to review, revise and, if necessary, develop new policies and procedure to ensure they comply with the requirements. The burden associated with reviewing, revising, and updating the CMHC's emergency policies and procedures will be due to the resources needed to ensure they comply with the requirements. We expect that the administrator and the psychiatric registered nurse will be involved with reviewing, revising and, if needed, developing any new policies and procedures. We estimate that for a CMHC to comply with this requirement will require 12 burden hours at a cost of $944. Therefore, for all 198 CMHCs to comply with this requirement will require an estimated 2,376 burden hours (12 burden hours for each CMHC × 198 CMHCs) at a cost of $186,912 ($944 estimated cost for each CMHC × 198 CMHCs).

TABLE 97—TOTAL COST ESTIMATE FOR A CMHC TO DEVELOP POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$94	4	$376
Psychiatric Registered Nurse	71	8	568
Total	....	12	944

The CMHCs will be required to review and update their emergency preparedness policies and procedures at least annually. For the purpose of determining the burden for this requirement, we expect that CMHCs will review their policies and procedures annually. We expect that all CMHCs have an administrator who is responsible for the day-to-day operation of the CMHC, which includes ensuring that all of the CMHC's policies and procedures are up-to-date and comply with the relevant federal, state, and local laws, regulations, and ordinances. We also expect that the administrator is responsible for periodically reviewing the emergency preparedness policies and procedures as part of his or her responsibilities. We expect that complying with the requirement for an annual review of the emergency preparedness policies and procedures will constitute a usual and customary business practice for CMHCs. As stated in the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information that will be incurred by persons in the normal course of their activities are not subject to the PRA.

Section 485.920(c) will require CMHCs to develop and maintain an emergency preparedness communications plan that complies with both federal and state law. The CMHC also will have to review and update this plan at least annually. The communication plan must include the information listed in § 485.920(c)(1) through (7).

We expect that all CMHCs will compare their current emergency preparedness communications plan, if they have one, to the requirements. CMHCs will need to perform any tasks necessary to ensure that their communication plans were documented and in compliance with the requirements.

We expect that all CMHCs have some type of emergency preparedness communications plan. However, their emergency communications plan may not be thoroughly documented or comply with all of the elements we are requiring. It is standard practice for healthcare organizations to maintain contact information for their staff and for outside sources of assistance; alternate means of communication in case there is a disruption in phone service to the facility (for example, cell phones); and a method for sharing information and medical documentation with other healthcare providers to ensure continuity of care for their patients. However, we expect that all CMHCs will need to review, update, and in some cases, develop new sections for their plans to ensure that those plans include all of the elements we are requiring for CMHC communications plans.

The burden associated with complying with this requirement will be due to the resources required to ensure that the CMHC's emergency communication plan complies with the requirements. Based upon our experience with CMHCs, we expect the involvement of the CMHC's administrator and the psychiatric registered nurse. For each CMHC, we estimate that complying with this requirement will require 8 burden hours at a cost of $637. Therefore, for all of the CMHCs to comply with this requirement will require an estimated 1,584 burden hours (8 burden hours for each CMHC × 198 CMHCs) at a cost of $126,126 ($637 estimated cost for each CMHC × 198 CMHCs).

TABLE 98—TOTAL COST ESTIMATE FOR A CMHC TO DEVELOP A COMMUNICATION PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$94	4	$282
Psychiatric Registered Nurse	71	5	355
Total	....	8	637

We expect that CMHCs must also review and update their emergency preparedness communication plan at least annually. For the purpose of determining the burden for this requirement, we expect that CMHCs will review their policies and procedures annually. We expect that all CMHCs have an administrator who is responsible for the day-to-day operation of the CMHC. This includes ensuring that all of the CMHC's policies and procedures are up-to-date and comply with the relevant federal, state, and local laws, regulations, and ordinances. We expect that the administrator is responsible for periodically reviewing the CMHC's plans, policies, and procedures as part of his or her responsibilities. In addition, we expect that an annual review of the communication plan will require only a negligible burden. Complying with the requirement for an annual review of the emergency preparedness communications plan constitutes a usual and customary business practice for CMHCs. As stated in the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information that will be incurred by persons in the normal course of their activities are not subject to the PRA.

Section 485.920(d) will require CMHCs to develop and maintain an emergency preparedness training program that must be reviewed and updated at least annually. We will require the CMHC to meet the requirements contained in § 485.920(d)(1) and (2).

We expect that CMHCs will develop a comprehensive emergency preparedness training program. The CMHCs will need to compare their current emergency preparedness training program and compare its contents to the risk assessment and updated emergency preparedness plan, policies and procedures, and communications plan and review, revise, and, if necessary, develop new sections for their training program to ensure it complies with the requirements.

The burden will be due to the resources the CMHC will need to comply with the requirements. We expect that complying with this requirement will include the involvement of a psychiatric registered nurse. We expect that the psychiatric registered nurse will be primarily involved in reviewing the CMHC's current training program, determining what tasks need to be performed or what materials need to be developed, and developing the materials for the training program. We estimate that it will require 10 burden hours for each CMHC to develop a comprehensive emergency training program at a cost of $710. Therefore, it will require an estimated 1,980 burden hours (10 burden hours for each CMHC × 198 CMHCs) to comply with this requirement at a cost of $140,580 ($710 estimated cost for each CMHC × 198 CMHCs).

TABLE 99—TOTAL COST ESTIMATE FOR A CMHC TO DEVELOP A TRAINING PROGRAM

Position	Hourly wage	Burden hours	Cost estimate
Psychiatric Registered Nurse	$71	10	$710

TABLE 99—TOTAL COST ESTIMATE FOR A CMHC TO DEVELOP A TRAINING PROGRAM—Continued

Position	Hourly wage	Burden hours	Cost estimate
Total	....	10	710

Section 485.920(d)(1) will also require the CMHCs to review and update their emergency preparedness training program at least annually. For the purpose of determining the burden for this requirement, we will expect that CMHCs will review their emergency preparedness training program annually. We expect that all CMHCs have a professional staff person, probably a psychiatric registered nurse, who is responsible for periodically reviewing their training program to ensure that it is up-to-date and complies with the relevant federal, state, and local laws, regulations, and ordinances. In addition, we expect that an annual review of the CMHC's emergency preparedness training program will require only a negligible burden. Thus, we expect that complying with the requirement for an annual review of the emergency preparedness training program constitutes a usual and customary business practice for CMHCs. As stated in the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information that will be incurred by persons in the normal course of their activities are not subject to the PRA.

Section 485.920(d)(2) will require CMHCs to participate in or conduct a full-scale exercise at least annually. CMHCs are also required to participate in one additional testing exercise of their choice at least annually. CMHCs will be required to document the drills and the exercises. To comply with this requirement, a CMHC will need to develop a specific scenario for each drill and exercise. A CMHC will have to develop the documentation necessary to record what happened during the drills and exercises.

Based on our experience with CMHCs, we expect that all 198 CMHCs have some type of emergency preparedness training program and most, if not all, of these CMHCs already conduct some type of drill or exercise to test their emergency preparedness plans. However, we do not know what type of drills or exercises they typically conduct or how often they are performed. We also do not know how, or if, they are documenting and analyzing their responses to these drills and tests. For the purpose of determining a burden for these requirements, we will expect that all CMHCs need to develop two scenarios, one for the drill and one for the exercise, and develop the documentation necessary to record the facility's responses.

The associated burden will be the time and effort necessary to comply with the requirement. We expect that complying with this requirement will likely require the involvement of a psychiatric registered nurse. We expect that the psychiatric registered nurse will develop the documentation necessary for both during the testing exercises and for the subsequent analysis of the CMHC's response. The psychiatric registered nurse will also develop the two scenarios for the drill and exercise. We estimate that these tasks will require 4 burden hours at a cost of $284. For all 198 CMHCs to comply with this requirement will require an estimated 792 burden hours (4 burden hours for each CMHC × 198 CMHCs) at a cost of $56,232 ($284 estimated cost for each CMHC × 198 CMHCs).

TABLE 100—TOTAL COST ESTIMATE FOR A CMHC TO CONDUCT TESTING

Position	Hourly wage	Burden hours	Cost estimate
Psychiatric Registered Nurse	$71	4	$284
Total	....	4	284

TABLE 101—BURDEN HOURS AND COST ESTIMATES FOR ALL 198 CMHCS TO COMPLY WITH THE ICRS CONTAINED IN § 485.920 EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 485.920(a)	0938–New	198	198	5	990	**	73,458	73,458
§ 485.920(a)(1)	0938–New	198	198	10	1,980	**	156,024	156,024
§ 485.920(a)(1)–(4)	0938–New	198	198	15	2,970	**	220,374	220,374
§ 485.920(b)	0938–New	198	198	12	2,376	**	186,912	186,912
§ 485.920(c)	0938–New	198	198	8	1,584	**	126,126	126,126
§ 485.920(d)(1)	0938–New	198	198	10	1,980	**	140,580	140,580
§ 485.920(d)(2)	0938–New	198	198	4	792	**	56,232	56,232
Totals	....	198	1,188	....	12,672	....	....	959,706

** The hourly labor cost is blended between the wages for multiple staffing levels.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 101.

Q. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 486.360)

Section 486.360(a) will require Organ Procurement Organizations (OPOs) to develop and maintain emergency preparedness plans that will have to be reviewed and updated at least annually. These plans will have to comply with the requirements listed in § 486.360(a)(1) through (4).

As of June 2016, there are 58 OPOs. The current OPO Conditions for Coverage (CfCs) are located at §§ 486.301 through 486.348. These CfCs do not contain any specific emergency preparedness requirements. Thus, for the purpose of determining the burden, we have analyzed the burden for all 58 OPOs for all of the ICRs contained in this final rule.

Section 486.360(a)(1) will require OPOs to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. OPOs will need to identify the medical and non-medical emergency events they could experience both at their facilities and in the surrounding area, including branch offices and hospitals in their donation services areas.

The burden associated with this requirement will be the time and effort necessary to perform a thorough risk assessment. Based on our experience with OPOs, we believe that all 58 OPOs have already performed at least some of the work needed for their risk assessments. However, these risk assessments may not be documented or may not address all of the elements required under § 486.360(a). Therefore, we expect that all 58 OPOs will have to perform a thorough review of their current risk assessments and perform the necessary tasks to ensure that their risk assessment complied with the requirements of this final rule. Based on our experience with OPOs, we believe that conducting a risk assessment will require the involvement of the OPO's director, medical director, quality assessment and performance improvement (QAPI) director, and an organ procurement coordinator (OPC). We expect that these individuals will attend an initial meeting; review relevant sections of the current assessment, prepare and send their comments to the QAPI director; attend a follow-up meeting; perform a final review; and approve the new risk assessment. We estimate that the QAPI director probably will coordinate the meetings, review the current risk assessment, critique the risk assessment, coordinate comments, develop the new risk assessment, and assure that the necessary parties approved it. We estimate that it will require 10 burden hours for each OPO to conduct a risk assessment at a cost of $1,190. Therefore, for all 58 OPOs to comply with the risk assessment requirement in this section will require an estimated 580 burden hours (10 burden hours for each OPO × 58 OPOs) at a cost of $69,020 ($1,190 estimated cost for each OPO × 58 OPOs).

TABLE 102—TOTAL COST ESTIMATE FOR AN OPO TO CONDUCT A RISK ASSESSMENT

Position	Hourly wage	Burden hours	Cost estimate
Director	$106	2	$212
Medical Director/Physician	207	2	414
QAPI Director	94	4	376
Organ Procurement Coordinator	94	2	188
Total		10	1,190

After conducting the risk assessment, OPOs will then have to develop emergency preparedness plans. The burden associated with this requirement will be the resources needed to develop an emergency preparedness plan that complied with the requirements in § 486.360(a)(1) through (4). We expect that all OPOs have some type of emergency preparedness plan because it is standard practice in the healthcare industry to have a plan to address common emergencies, such as fires. In addition, based on our experience with OPOs (including the performance of the Louisiana OPO during the Katrina disaster), OPOs already have plans to ensure that services will continue to be provided in their donation service areas (DSAs) during an emergency. However, we do not expect that all OPOs will have emergency preparedness plans that will satisfy the requirements of this section. Therefore, we expect that all OPOs will need to review their current emergency preparedness plans and compare their plans to their risk assessments. Most OPOs will need to revise, and in some cases develop, new sections to ensure their plan satisfied the requirements.

We expect that the same individuals who were involved in the risk assessment will be involved in developing the emergency preparedness plan. We expect that these individuals will attend an initial meeting, review relevant sections of the OPO's current emergency preparedness plan, prepare and send their comments to the QAPI director, attend a follow-up meeting, perform a final review, and approve the new plan. We expect that the QAPI Director will coordinate the meetings, perform an initial review of the current emergency preparedness plan, critique the emergency preparedness plan, coordinate comments, ensure that the appropriate individuals revise the plan, and ensure that the necessary parties approve the new plan.

Thus, we estimate that it will require 22 burden hours for each OPO to develop an emergency preparedness plan that complied with the requirements of this section at a cost of $2,568. The difference in burden between the risk assessment and the plan requirement is greater in this section because OPOs have multiple locations and personnel in various locations. Therefore, for all 58 OPOs to comply with this requirement will require an estimated 1,276 burden hours (22 burden hours for each OPO × 58 OPOs) at a cost of $148,944 ($2,568 estimated cost for each OPO × 58 OPOs).

TABLE 103—TOTAL COST ESTIMATE FOR AN OPO TO DEVELOP AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Director	$106	4	$424
Medical Director/Physician	207	4	828

TABLE 103—TOTAL COST ESTIMATE FOR AN OPO TO DEVELOP AN EMERGENCY PREPAREDNESS PLAN—Continued

Position	Hourly wage	Burden hours	Cost estimate
QAPI Director	94	10	940
Organ Procurement Coordinator	94	4	376
Total	....	22	2,568

The OPOs will also be required to review and update their emergency preparedness plans at least annually. We believe that all of the OPOs already review their emergency preparedness plans periodically. However, the current OPO CoPs do not include a requirement for an emergency preparedness plan and as such, there is no requirement for an annual review of the plan. Therefore, we will analyze the burden from this requirement for all OPOs.

Based on our experience with OPOs, we expect that the same individuals who develop the emergency preparedness plan will annually review and update the plan. We expect that the QAPI director will spend more time than the director, medical director, and organ procurement coordinator on the review of the plan and documentation of the plan updates. We estimate that for each OPO to comply will require 6 burden hours at a cost of $689. Based on that estimate, it will require 348 burden hours (6 burden hours for each organization × 58 organizations) at a cost of $39,962 ($689 estimated cost for each organization × 58 organizations).

TABLE 104—TOTAL ESTIMATED COST FOR AN OPO TO REVIEW AND UPDATE AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Director	$106	1	$106
Medical Director/Physician	207	1	207
QAPI Director	94	3	282
Organ Procurement Coordinator	94	1	94
Total	....	6	689

Section 486.360(b) will require OPOs to develop and maintain emergency preparedness policies and procedures based on their risk assessments, emergency preparedness plans, emergency communication plan as set forth in § 486.360(a)(1), (a), and (c), respectively. It will also require OPOs to review and update these policies and procedures at least annually. The OPO's policies and procedures must address the requirements listed at § 486.360(b)(1) and (2).

The OPO CfCs already require the OPOs' governing body to develop and oversee implementation of policies and procedures considered necessary for the effective administration of the OPO, including the OPO's quality assessment and performance improvement (QAPI) program, and services furnished under contract or arrangement, including agreements for those services (§ 486.324(e)). Thus, we expect that OPOs already have developed and implemented policies and procedures for their effective administration. However, since the current CfCs have no specific requirement that these policies and procedures address emergency preparedness, we do not believe that the OPOs have developed or implemented all of the policies and procedures that will be needed to comply with the requirements of this section.

The burden associated with the development of the emergency preparedness policies and procedures will be the resources needed to develop emergency preparedness policies and procedures that will include, but will not be limited to, the specific elements identified in this requirement. We expect that all OPOs will need to review their current policies and procedures and compare them to their risk assessments, emergency preparedness plans, emergency communication plans, and agreements and protocols; they have developed as required by this final rule. Following their reviews, OPOs will need to develop and implement the policies and procedures necessary to ensure that they initiate and maintain their emergency preparedness plans, agreements, and protocols.

Based on our experience with OPOs, we expect that accomplishing these activities will require the involvement of the OPO's director, medical director, QAPI director, and an Organ Procurement Coordinator (OPC). We expect that all of these individuals will review the OPO's current policies and procedures; compare them to the risk assessment, emergency preparedness plan, agreements and protocols they have established with hospitals, other OPOs, and transplant programs; provide an analysis or comments; and participate in developing the final version of the policies and procedures.

We expect that the QAPI director will likely coordinate the meetings; coordinate and incorporate comments; draft the revised or new policies and procedures; and obtain the necessary signatures for final approval. We estimate that it will require 20 burden hours for each OPO to comply with the requirement to develop emergency preparedness policies and procedures at a cost of $2,154. Therefore, for all 58 OPOs to comply with this requirement will require an estimated 1,160 burden hours (20 burden hours for each OPO × 58 OPOs) at a cost of $124,932 (estimated cost for each OPO of $2,154 × 58 OPOs).

TABLE 105—TOTAL COST ESTIMATE FOR AN OPO TO DEVELOP POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Director	$106	4	$424
Medical Director/Physician	207	2	414

TABLE 105—TOTAL COST ESTIMATE FOR AN OPO TO DEVELOP POLICIES AND PROCEDURES—Continued

Position	Hourly wage	Burden hours	Cost estimate
QAPI Director	94	8	752
Organ Procurement Coordinator	94	6	564
Total	....	20	2,154

The OPOs also will be required to review and update their emergency preparedness policies and procedures at least annually. We believe that OPOs already review their emergency preparedness policies and procedures periodically. Therefore, we believe compliance with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 486.360(c) will require OPOs to develop and maintain emergency preparedness communication plans that complied with both federal and state law. The OPOs will have to review and update their plans at least annually. The communication plans will have to include the information listed in § 486.360(c)(1) through (3).

The OPOs must operate 24 hours a day, 7 days a week. OPOs conduct much of their work away from their office(s) at various hospitals within their DSAs. To function effectively, OPOs must ensure that they and their staff at these multiple locations can communicate with the OPO's office(s), other OPO staff members, transplant and donor hospitals, transplant programs, the Organ Procurement and Transplantation Network (OPTN), other healthcare providers, other OPOs, and potential and actual donors' next-of-kin.

Thus, we expect that the nature of their work will ensure that all OPOs have already addressed at least some of the elements that will be required by this section. For example, due to the necessity of communication with so many other entities, we expect that all OPOs will have compiled names and contact information for staff, other OPOs, and transplant programs.

We also expect that all OPOs will have alternate means of communication for their staffs. However, we do not believe that all OPOs have developed formal plans that include all of the elements contained in this requirement. The burden will be the resources needed to develop an emergency preparedness communications plan that will include, but not be limited to, the specific elements identified in this section. We expect that this will require the involvement of the OPO director, medical director, QAPI director, and OPC. We expect that all of these individuals will need to review the OPO's current plans, policies, and procedures related to communications and compare them to the OPO's risk assessment, emergency plan, and the agreements and protocols the OPO developed in accordance with § 486.360(e), and the OPO's emergency preparedness policies and procedures. We expect that these individuals will review the materials described earlier, submit comments to the QAPI director, review revisions and additions, and give a final recommendation or approval for the new emergency preparedness communication plan. We also expect that the QAPI director will coordinate the meetings; compile comments; incorporate comments into a new communications plan, as appropriate; and ensure that the necessary individuals review and approve the new plan.

We estimate that it will require 14 burden hours to develop an emergency preparedness communication plan at a cost of $1,566. Therefore, it will require an estimated 812 burden hours (14 burden hours for each OPO × 58 OPOs) at a cost of $90,828 ($1,566 estimated cost for each OPO × 58 OPOs).

TABLE 106—TOTAL COST ESTIMATE FOR AN OPO TO DEVELOP A COMMUNICATION PLAN

Position	Hourly wage	Burden hours	Cost estimate
Director	$106	2	$212
Medical Director/Physician	207	2	414
QAPI Director	94	6	564
Organ Procurement Coordinator	94	4	376
Total	....	14	1,566

We proposed that OPOs must review and update their emergency preparedness communication plans at least annually. We believe that all of the OPOs already review their emergency preparedness communication plans periodically. Thus, we believe compliance with this requirement will constitute a usual and customary business practice for OPOs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 486.360(d) will require OPOs to develop and maintain emergency preparedness training and testing programs. OPOs also will be required to review and update these programs at least annually. In addition, OPOs must meet the requirements listed in § 486.360(d)(1) and (2).

In § 486.360(d)(1), we proposed that OPOs be required to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of that training. OPOs must also ensure that their staff can demonstrate knowledge of their emergency procedures. Thereafter, OPOs will have to provide emergency preparedness training at least annually.

Under existing regulations, OPOs are required to provide their staffs with the training and education necessary for them to furnish the services the OPO is required to provide, including applicable organizational policies and procedures and QAPI activities (§ 486.326(c)). However, since there are no specific emergency preparedness requirements in the current OPO CfCs, we do not believe that the content of their existing training will comply with the requirements.

We expect that OPOs will develop a comprehensive emergency preparedness training program for their staffs. Based upon our experience with OPOs, we expect that complying with this requirement will require the OPO director, medical director, the QAPI director, an OPC, and the education coordinator. We expect that the QAPI director and the education coordinator will review the OPO's risk assessment, emergency preparedness plan, policies and procedures, and communication plan and make recommendations regarding revisions or new sections necessary to ensure that all appropriate information is included in the OPO's emergency preparedness training. We believe that the OPO director, medical director, and OPC will meet with the QAPI director and education coordinator and assist in the review, provide comments, and approve the new emergency preparedness training program.

We estimate that it will require 40 burden hours for each OPO to develop an emergency preparedness training program that complied with these requirements at a cost of $3,154. Therefore, we estimate that for all 58 OPOs to comply with this requirement will require 2,320burden hours (40 burden hours for each OPO × 58 OPOs) at a cost of $203,812 ($3,514 estimated cost for each OPO × 58 OPOs).

TABLE 107—TOTAL COST ESTIMATE FOR AN OPO TO DEVELOP A TRAINING PROGRAM

Position	Hourly wage	Burden hours	Cost estimate
Director	$106	2	$212
Medical Director/Physician	207	2	414
QAPI Director	94	12	1,128
Organ Procurement Coordinator	94	8	752
Education Coordinator	63	16	1,008
Total	....	40	3,514

We proposed that OPOs must review and update their emergency preparedness training programs at least annually. We believe that all of the OPOs already review their emergency preparedness training programs periodically. Therefore, we believe compliance with this requirement will constitute a usual and customary business practice for OPOs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 486.360(d)(2) will require OPOs to conduct a paper-based, tabletop exercise at least annually. OPOs also will be required to analyze their responses to and maintain documentation of all tabletop exercises and actual emergency events, and revise their emergency plans, as needed. To comply with this requirement, OPOs will have to develop scenarios for each tabletop exercise and the necessary documentation.

The OPO CfCs do not currently contain a requirement for OPOs to conduct a paper-based, tabletop exercise. However, OPOs are required to evaluate their staffs' performance and provide training to improve individual and overall staff performance and effectiveness (42 CFR 486.326(c)). Therefore, we expect that OPOs periodically conduct some type of exercise to test their plans, policies, and procedures, which will include developing a scenario for and documenting the exercise. Thus, we believe compliance with these requirements will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

We expect that the QAPI director and the education coordinator will work together to develop the scenario for the exercise and the necessary documentation. We expect that the QAPI director will likely spend more time on these activities. We estimate that these tasks will require 5 burden hours for each OPO at a cost of $408. For all 58 OPOs to comply with these requirements will require an estimated 290 burden hours (5 burden hours for each OPO × 58 OPOs) at a cost of $23,664 ($408 estimated cost for each OPO × 58 OPOs).

TABLE 108—TOTAL COST ESTIMATE FOR AN OPO TO CONDUCT TESTING

Position	Hourly wage	Burden hours	Cost estimate
QAPI Director	$94	3	$282
Education Coordinator	63	2	126
Total	....	5	408

Section 486.360(e) requires OPOs to develop and maintain mutually agreed upon protocols as required in § 486.344(d) that cover the duties and responsibilities of the transplant program, the hospital in which the transplant program is operated and the OPO during an emergency. Section 486.344(d) does not currently require that emergency preparedness be addressed in those protocols. Thus, we believe that most OPOs do not currently address emergency preparedness in their protocols. OPOs will only be required to address emergency preparedness with the transplant centers and the hospitals in which they operate. Since the number of transplant hospitals varies between the DSAs and the number of transplant programs in each of those hospitals also varies, we have estimated the burden based on the average number of transplant hospitals for each DSA and the number of transplant programs in those hospitals. There are about 770 transplant programs and 234 transplant hospitals. For each OPO's DSA, there is an average of 4 transplant hospitals (234 transplant hospitals/58 OPOs) with 3 transplant programs (770 transplant programs/234 transplant hospitals). Thus, we estimate that each OPO would need to develop

protocols for 12 transplant programs (4 transplant hospitals for each DSA × 3 transplant programs in each transplant hospital).

The burden associated with this requirement will be the time and effort necessary to negotiate with each hospital and transplant program, and then draft the protocols that address each one's duties and responsibilities during an emergency. Based on our experience with OPOs, transplant centers, and the hospitals in which they operate, we believe that they have already had to deal with some type of emergency and have a basis for those protocols, especially the types of services that are needed by the waiting list patients and the transplant recipients and the services that each of them can provide during an emergency. Based on our experience with OPOs, we believe that conducting these negotiations would require the involvement of the OPO's director, medical director, QAPI director, and an organ procurement coordinator (OPC). We expect that these individuals would attend an initial meeting and then one individual, probably the QAPI director, would draft the protocols and ensure they are reviewed by all required parties and agreed to. This would require an hour of each individual's time, except for the QAPI director who would require 2 hours for each transplant program. Thus, for each transplant program, the OPO would need 5 burden hours at a cost of $595. As described previously, each OPO would need to develop protocols for 12 transplant programs. Thus, to comply with this requirement, each OPO would require 60 burden hours (5 burden hours × 12 transplant programs) at a cost of $7,140 ($595 for each transplant program × 12 transplant programs). For all 58 OPOs, we estimate that the total burden to develop these protocols would be 3,480 burden hours (60 burden hours for each OPO × 58 OPOs) at a cost of $414,120 ($7,140 for each OPO × 58 OPOs).

TABLE 109—TOTAL COST ESTIMATE FOR AN OPO TO DEVELOP AND MAINTAIN MUTUALLY AGREED UPON PROTOCOLS

Position	Hourly wage	Burden hours	Cost estimate
Director	$106	1	$106
Medical Director/Physician	207	1	207
QAPI Director	94	2	188
Organ Procurement Coordinator	94	1	94
Total	....	5	595

Section 486.360(e) will also require each OPO to have the capability to continue its operations from an alternate location during an emergency. The OPO can have an agreement with one or more other OPOs to provide essential organ procurement services to all or a portion of the OPO's DSA in the event that the OPO cannot provide such services due to an emergency. However, based upon comments that we received, we are also finalizing two alternate means by which an OPO can also comply with this requirement. An OPO with more than one location or office would satisfy this requirement if it had at least one other location or office from which the OPO could conduct its operations, or at least those services the OPO has deemed essential to provide, during an emergency. An OPO could also satisfy this requirement by having a plan, which has been positively tested, to locate to an alternate location during an emergency as part of its emergency plan as required by § 486.360(a). According to the commenters, some OPOs, especially those in DSAs that cover large geographical areas, already have more than one office or location. In addition, since OPOs will have to address continuity of operations in their emergency plans under § 486.360(a), we believe that virtually all of the OPOs will chose to comply with this requirement by one of the two alternate methods being finalized. We estimate that about 9 OPOs or 15 percent of all OPOs would chose to have an agreement with another OPO. Since we estimate that fewer than 10 OPOs would chose to have an agreement with another OPO, this requirement is not subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(c).

TABLE 110—BURDEN HOURS AND COST ESTIMATES FOR ALL 58 OPOS TO COMPLY WITH THE ICRS CONTAINED IN § 486.360 EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 486.360(a)	0938–New	58	58	6	348	**	39,962	39,962
§ 486.360(a)(1)	0938–New	58	58	10	580	**	69,020	69,020
§ 486.360(a)(2)–(4)	0938–New	58	58	22	1,276	**	148,944	148,944
§ 486.360(b)	0938–New	58	58	20	1,160	**	124,932	124,932
§ 486.360(c)	0938–New	58	58	14	812	**	90,828	90,828
§ 486.360(d)(1)	0938–New	58	58	40	2,320	**	203,812	203,812
§ 486.360(d)(2)	0938–New	58	58	5	290	**	23,664	23,664
§ 486.360(e)	0938–New	58	58	60	3,480	**	414,120	414,120
Totals	....	58	406	....	10,266	....	....	1,115,282

** The hourly labor cost is blended between the wages for multiple staffing levels.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 110.

R. ICRs Regarding Condition for Coverage and Condition for Certification: Emergency Preparedness (§ 491.12)

Section 491.12(a) will require Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) to develop and maintain emergency preparedness plans. The RHCs and FQHCs will also have to review and update their plans at least annually. We proposed that the plan must meet the requirements listed at § 491.12(a)(1) through (4).

Section 491.12(a)(1) will require RHCs/FQHCs to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. RHCs/FQHCs will need to identify the medical and non-medical emergency events they could experience both at their facilities and in the surrounding area. RHCs/FQHCs will need to review any existing risk assessments and then update and revise those assessments or develop new sections for them so that those assessments complied with our requirements.

We obtained the total number of RHCs and FQHCs used in this burden analysis from the CMS CASPER data system, which the states update periodically. Due to variations in the timeliness of the data submission, all numbers in this analysis are approximate. There are currently 11,500 RHC/FQHCs (4,200 RHCs + 7,300 FQHCs). Unlike RHCs, FQHCs are grantees and look-alikes under HRSA's Health Center Program. In 2007, the Health Resources and Services Administration (HRSA) issued a Policy Information Notice (PIN) entitled "Health Center Emergency Management Program Expectations," that detailed the expectations HRSA has for health centers related to emergency management ("Health Center Emergency Management Program Expectations," Policy Information Notice (PIN), Document Number 2007–15, HRSA, August 22, 2007) (Emergency Management PIN). A review of the Emergency Management PIN indicates that some of its expectations are very similar to the requirements in this final rule. While the expectations set forth by HRSA in the Emergency Management PIN are not requirements for receiving a HRSA Center Program grant (and as such are not requirements for FQHCs), if HRSA finds that an FQHC is not meeting the expectations of the Emergency Management PIN, it would provide the FQHC with resources for technical assistance to assist them in meeting these expectations. This demonstrates the importance of the FQHC's compliance with the Emergency Management PIN guidance. Therefore, since the expectations in the Emergency Management PIN are a significant factor in determining the burden for FQHCs, we will analyze the burden for the 7,300 FQHCs separately from the 4,200 RHCs where the burden will be significantly different.

Based on our experience with RHCs, we expect that all 4,200 RHCs have already performed at least some of the work needed to conduct a risk assessment. It is standard practice for healthcare facilities to prepare for common emergencies, such as fires, power outages, and storms. In addition, the current Rural Health Clinic Conditions for Certification and the FQHC Conditions for Coverage (RHC/FQHC CfCs) already require each RHC and FQHC to assure the safety of patients in case of non-medical emergencies by taking other appropriate measures that are consistent with the particular conditions of the area in which the clinic or center is located (§ 491.6(c)(3)).

Furthermore, in accordance with the Emergency Management PIN, FQHCs should have initiated their "emergency management planning by conducting a risk assessment such as a Hazard Vulnerability Analysis" (HVA) (Emergency Management PIN, p. 5). The HVA should identify potential emergencies or risks and potential direct and indirect effects on the facility's operations and demands on their services and prioritize the risks based on the likelihood of each risk occurring and the impact or severity the facility will experience if the risk occurs (Emergency Management PIN, p. 5). FQHCs are also "encouraged to participate in community level risk assessments and integrate their own risk assessment with the local community" (Emergency Management PIN, p. 5).

Despite these expectations and the existing Medicare regulations for RHCs/FQHCs, some RHC/FQHC risk assessments may not comply with all requirements. For example, the expectations for FQHCs do not specifically address our requirement to address likely medical and non-medical emergencies. In addition, participation in a community-based risk assessment is only encouraged, not required. We expect that all 4,200 RHCs and 6,502 FQHCs will need to compare their current risk assessments with our requirements and accomplish the tasks necessary to ensure their risk assessments comply with our requirements. However, we expect that FQHCs will not be subject to as many burden hours as RHCs.

We have not designated any specific process or format for RHCs or FQHCs to use in conducting their risk assessments because we believe that RHCs and FQHCs need flexibility to determine the best way to accomplish this task. However, we expect that these healthcare facilities will include input from all of their major departments. Based on our experience with RHCs/FQHCs, we expect that conducting the risk assessment will require the involvement of the RHC/FQHC's administrator, a physician, a nurse practitioner or physician assistant, and a registered nurse. We expect that these individuals will attend an initial meeting, review the current risk assessment, prepare and forward their comments to the administrator, attend a follow-up meeting, perform a final review, and approve the new risk assessment. We expect that the administrator will coordinate the meetings, review the current risk assessment, provide an analysis of the risk assessment, offer suggested revisions, coordinate comments, develop the new risk assessment, and ensure that the necessary parties approve it. We also expect that the administrator will spend more time reviewing the risk assessment than the other individuals.

We estimate that it will require 10 burden hours for each RHC to conduct a risk assessment that complied with the requirements in this section at a cost of $1,080. We estimate that for all RHCs to comply with our requirements will require 42,000 burden hours (10 burden hours for each RHC × 4,200 RHCs) at a cost of $4,536,000 ($1,080 estimated cost for each RHC × 4,200 RHCs).

TABLE 111—TOTAL ESTIMATED COST FOR A RHC TO CONDUCT A RISK ASSESSMENT

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	4	$388
Medical Director/Physician	181	2	362
Nurse Practitioner/Physician Assistant	94	2	188

TABLE 111—TOTAL ESTIMATED COST FOR A RHC TO CONDUCT A RISK ASSESSMENT—Continued

Position	Hourly wage	Burden hours	Cost estimate
Registered Nurse	71	2	142
Total		10	1,080

We estimate that it will require 5 burden hours for each FQHC to conduct a risk assessment that complied with our requirements at a cost of $520. We estimate that for all 7,300 FQHCs to comply will require 36,500 burden hours (5 burden hours for each FQHC × 7,300 FQHCs) at a cost of $3,796,000 ($520 estimated cost for each FQHC × 7,300 FQHCs). Based on those estimates, compliance with this requirement for all RHCs and FQHCs will require 78,500 burden hours at a cost of $8,332,000.

TABLE 112—TOTAL ESTIMATED COST FOR AN FQHC TO CONDUCT A RISK ASSESSMENT

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	2	$194
Medical Director/Physician	181	1	181
Nurse Practitioner/Physician Assistant	94	1	94
Registered Nurse	51	1	51
Total		5	520

After conducting the risk assessment, RHCs/FQHCs will have to develop and maintain emergency preparedness plans that complied with § 491.12(a)(1) through (4) and review and update them annually. It is standard practice for healthcare facilities to plan for common emergencies, such as fires, hurricanes, and snowstorms. In addition, as discussed earlier, we require all RHCs/FQHCs to take appropriate measures to ensure the safety of their patients in non-medical emergencies, based on the particular conditions present in the area in which they are located (§ 491.6(c)(3)). Thus, we expect that all RHCs/FQHCs have developed some type of emergency preparedness plan. However, under this final rule, all RHCs/FQHCs will have to review their current plans and compare them to their risk assessments. The RHCs/FQHCs will need to update, revise, and, in some cases, develop new sections to complete their emergency preparedness plans that meet our requirements.

The Emergency Management PIN contains many expectations for an FQHC's emergency management plan (EMP). For example, it states that the FQHC's EMP "is necessary to ensure the continuity of patient care" during an emergency (Emergency Management PIN, p. 6) and should contain plans for "assuring access for special populations (Emergency Management PIN, p. 7). The FQHC's EMP also should address continuity of operations, as appropriate (Emergency Management PIN, p. 6). In addition, FQHCs should use an "all-hazards approach" so that these facilities can respond to all of the risks they identified in their risk assessment (Emergency Management PIN, p. 6). Based on the expectations in the Emergency Management PIN, we expect that FQHCs likely have developed emergency preparedness plans that comply with many, if not all, of the elements with which their plans will need to comply under this final rule. However, we expect that FQHCs will need to compare their current EMP to our requirements and, if necessary, revise or develop new sections for their EMP to bring it into compliance. We expect that FQHCs will have less of a burden than RHCs.

Based on our experience with RHCs/FQHCs, we expect that the same individuals who were involved in developing the risk assessments will be involved in developing the emergency preparedness plans. However, we expect that it will require more time to complete the plans than the risk assessments. We expect that the administrator will have primary responsibility for reviewing and developing the RHC/FQHC's EMP. We expect that the physician, nurse practitioner or physician assistant, and registered nurse will review the draft plan and provide comments to the administrator. We estimate that for each RHC to comply with this requirement will require 14 burden hours at a cost of $1,379. Therefore, it will require an estimated 58,800 burden hours (14 burden hours for each RHC × 4,200 RHCs) to complete the plan at a cost of $5,791,800 ($1,379 estimated cost for each RHC × 4,200 RHCs).

TABLE 113—TOTAL ESTIMATED COST FOR A RHC TO DEVELOP AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	6	$582
Medical Director/Physician	181	2	362
Nurse Practitioner/Physician Assistant	94	3	282
Registered Nurse	51	3	153
Total		14	1,379

We estimate that it will require 8 burden hours for each FQHC to comply with our requirements at a cost of $762. Based on that estimate, it will require 58,400 burden hours (8 burden hours for each FQHC × 7,300 FQHCs) to complete the plan at a cost of $5,562,600 ($762 estimated cost for each FQHC × 7,300 FQHCs).

TABLE 114—TOTAL ESTIMATED COST FOR A FQHC TO DEVELOP AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	3	$291
Medical Director/Physician	181	1	181
Nurse Practitioner/Physician Assistant	94	2	188
Registered Nurse	51	2	102
Total	....	8	762

Based on the previous estimates, for all RHCs and FQHCs to develop an emergency preparedness plan that complies with our requirements will require 117,200 burden hours at a cost of $11,354,400.

Each RHC/FQHC also will be required to review and update its emergency preparedness plan at least annually. We believe that RHCs and FQHCs already review their emergency preparedness plans periodically. Thus, we believe compliance with this requirement will constitute a usual and customary business practice for RHCs and FQHCs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 491.12(b) will require RHCs/FQHCs to develop and implement emergency preparedness policies and procedures based on their emergency plans, risk assessments, and communication plans as set forth in § 491.12(a), (a)(1), and (c), respectively. We will also require RHCs/FQHCs to review and update these policies and procedures at least annually. At a minimum, we will require that the RHC/FQHC's policies and procedures address the requirements listed at § 491.12(b)(1) through (4).

We expect that all RHCs/FQHCs have some emergency preparedness policies and procedures. All RHCs and FQHCs are required to have emergency procedures related to the safety of their patients in non-medical emergencies (§ 491.6(c)). They also must set forth in writing their organization's policies (§ 491.7(a)(2)). In addition, current regulations require that a physician, in conjunction with a nurse practitioner or physician's assistant, develop the facility's written policies (§ 491.8(b)(ii) and (c)(i)). However, we expect that all RHCs/FQHCs will need to review their policies and procedures, assess whether their policies and procedures incorporate their risk assessments and emergency preparedness plans and make any changes necessary to comply with our requirements.

We expect that FQHCs already have policies and procedures that will comply with some of our requirements. Several of the expectations of the Emergency Management PIN address specific elements in § 491.12(b). For example, the PIN states that FQHCs should address, as appropriate, continuity of operations, staffing, surge patients, medical and non-medical supplies, evacuation, power supply, water and sanitation, communications, transportation, and the access to and security of medical records (Emergency Management PIN, p. 6). In addition, FQHCs should also continually evaluate their EMPs and make changes to their EMPs as necessary (Emergency Management PIN, p. 7). These expectations also indicate that FQHCs should be working with and integrating their planning with their state and local communities' plans, as well as other key organizations and other relationships (Emergency Management PIN, p. 8). Thus, we expect that burden for FQHCs from the requirement for emergency preparedness policies and procedures will be less than the burden for RHCs.

The burden associated with our requirements will be reviewing, revising, and, if needed, developing new emergency preparedness policies and procedures. We expect that a physician and a nurse practitioner will primarily be involved with these tasks and that an administrator will assist them. We estimate that for each RHC to comply with our requirements will require 12 burden hours at a cost of $1,482. Based on that estimate, for all 4,200 RHCs to comply with these requirements will require 50,400 burden hours (12 burden hours for each RHC × 4,200 RHCs) at a cost of $6,224,400 ($1,482 estimated cost for each RHC × 4,200 RHCs).

TABLE 115—TOTAL ESTIMATED COST FOR A RHC TO DEVELOP POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	2	$194
Medical Director/Physician	181	4	724
Nurse Practitioner/Physician Assistant	94	6	564
Total	....	12	1,482

As discussed earlier, we expect that FQHCs will have less of a burden from developing their emergency preparedness policies and procedures due to the expectations set out in the Emergency Management PIN. Thus, we estimate that for each FQHC to comply with the requirements will require 8 burden hours at a cost of $932. Based on that estimate, for all 7,300 FQHCs to comply with these requirements will require 58,400 burden hours (8 burden hours for each FQHC × 7,300 FQHCs) at a cost of $6,803,600 ($932 estimated cost for each FQHC × 7,300 FQHCs).

TABLE 116—TOTAL ESTIMATED COST FOR A FQHC TO DEVELOP POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	2	$194
Medical Director/Physician	181	2	362
Nurse Practitioner/Physician Assistant	94	4	376
Total		8	932

Based on the previous estimates, for all RHCs and FQHCs to develop emergency preparedness policies and procedures that comply with our requirements will require 108,800 burden hours at a cost of $13,028,000.

We proposed that RHCs/FQHCs review and update their emergency preparedness policies and procedures at least annually. We believe that RHCs and FQHCs already review their emergency preparedness policies and procedures periodically. Therefore, we believe compliance with this requirement will constitute a usual and customary business practice for RHCs/FQHCs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 491.12(c) will require RHCs/FQHCs to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. RHCs/FQHCs will also have to review and update these plans at least annually. We proposed that the communication plan must include the information listed in § 491.12(c)(1) through (5).

We expect that all RHCs/FQHCs have some type of emergency preparedness communication plan. It is standard practice for healthcare facilities to maintain contact information for staff and outside sources of assistance; alternate means of communication in case there is an interruption in the facility's phone services; and a method for sharing information and medical documentation with other healthcare providers to ensure continuity of care for patients. As discussed earlier, RHCs and FQHCs are required to take appropriate measures to ensure the safety of their patients during non-medical emergencies (§ 491.6(c)). We expect that an emergency preparedness communication plan will be an essential element in any emergency preparedness preparations. However, some RHCs/FQHCs may not have a formal, written emergency preparedness communication plan or their plan may not include all the requirements we proposed.

The Emergency Management PIN contains specific expectations for communications and information sharing (Emergency Management PIN, pp. 8–9). "A well-defined communication plan is an important component of an effective EMP" (Emergency Management PIN, p. 8). In addition, FQHCs are expected to have policies and procedures for communicating with both internal stakeholders (such as patients and staff) and external stakeholders (such as federal, tribal, state, and local agencies), and for identifying who will do the communicating and what type of information will be communicated (Emergency Management PIN, p. 8). FQHCs should also identify alternate communications systems in the event that their standard communications systems become unavailable, and the FQHC should identify these alternate systems in their EMP (Emergency Management PIN, p. 9). Thus, we expect that all FQHCs will have a formal communication plan for emergencies and that those plans will contain some of our requirements. However, we expect that all FQHCs will need to review, revise, and, if needed, develop new sections for their emergency preparedness communication plans to ensure that their plans are in compliance. We expect that these tasks will require less of a burden for FQHCs than for the RHCs.

The burden associated with complying with this requirement will be the resources required to review, revise, and, if needed, develop new sections for the RHC/FQHC's emergency preparedness communication plan. Based on our experience with RHCs/FQHCs, as well as the requirements in current regulations for a physician to work in conjunction with a nurse practitioner or a physician assistant to develop policies, we anticipate that satisfying the requirements in this section will require the involvement of the RHC/FQHC's administrator, a physician, and a nurse practitioner or physician assistant. We expect that the administrator and the nurse practitioner or physician assistant will be primarily involved in reviewing, revising, and if needed, developing new sections for the RHC/FQHC's emergency preparedness communication plan.

We estimate that for each RHC to comply with the requirements will require 10 burden hours at a cost of $1,126. Based on that estimate, for all 4,200 RHCs to comply will require 42,000 burden hours (10 burden hours for each RHC × 4,200 RHCs) at a cost of $4,729,200 ($1,126 estimated cost for each RHC × 4,200 RHCs).

TABLE 117—TOTAL ESTIMATED COST FOR A RHC TO DEVELOP A COMMUNICATION PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	4	$388
Medical Director/Physician	181	2	362
Nurse Practitioner/Physician Assistant	94	4	376
Total		10	1,126

We estimate that for a FQHC to comply with the requirements will require 5 burden hours at a cost of $563. Based on this estimate, for all 7,300 FQHCs to comply will require 36,500 burden hours (5 burden hours for each FQHC × 7,300 FQHCs) at a cost of $4,109,900 ($563 estimated cost for each FQHC × 7,300 FQHCs).

TABLE 118—TOTAL ESTIMATED COST FOR A FQHC TO DEVELOP A COMMUNICATION PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	2	$194
Medical Director/Physician	181	1	181
Nurse Practitioner/Physician Assistant	94	2	188
Total	....	5	563

We proposed that RHCs/FQHCs also review and update their emergency preparedness communication plans at least annually. We believe that RHCs/FQHCs already review their emergency preparedness communication plans periodically. Thus, we believe compliance with this requirement will constitute a usual and customary business practice for RHCs/FQHCs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 491.12(d) will require RHCs/FQHCs to develop and maintain emergency preparedness training and testing programs and review and update these programs at least annually. We proposed that an RHC/FQHC will have to comply with the requirements listed in § 491.12(d)(1) and (2).

Section 491.12(d)(1) will require each RHC and FQHC to provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of that training. Each RHC and FQHC will also have to ensure that its staff could demonstrate knowledge of those emergency procedures. Thereafter, each RHC and FQHC will be required to provide emergency preparedness training annually.

Based on our experience with RHCs and FQHCs, we expect that all 11,500 RHC/FQHCs already have some type of emergency preparedness training program. The current RHC/FQHC regulations require RHCs and FQHCs to provide training to their staffs on handling emergencies (§ 491.6(c)(1)). In addition, FQHCs are expected to provide ongoing training in emergency management and their facilities' EMP to all of their employees (Emergency Management PIN, p. 7). However, neither the current regulations nor the PIN's expectations for FQHCs address initial training and ongoing training, frequency of training, or requirements that individuals providing services under arrangement and volunteers be included in the training. RHCs/FQHCs will need to review their current training programs; compare their contents to their risk assessments, emergency preparedness plans, policies and procedures, and communication plans and then take the necessary steps to ensure that their training programs comply with our requirements.

We expect that each RHC and FQHC has a professional staff person who is responsible for ensuring that the facility's training program is up-to-date and complies with all federal, state, and local laws and regulations. This individual will likely be an administrator. We expect that the administrator will be primarily involved in reviewing the RHC/FQHC's emergency preparedness program; determining what tasks need to be performed and what materials need to be developed to bring the training program into compliance with our requirements; and making changes to current training materials and developing new training materials. We expect that the administrator will work with a registered nurse to develop the revised and updated training program. We estimate that it will require 10 burden hours for each RHC or FQHC to develop a comprehensive emergency training program at a cost of $602. Therefore, it will require an estimated 115,500 burden hours (10 burden hours for each RHC/FQHC × 11,500 RHCs/FQHCs) to comply with this requirement at a cost of $6,923,000 ($602 estimated cost for each RHC/FQHC × 11,500 RHCs/FQHCs).

TABLE 119—TOTAL ESTIMATED COST FOR A RHC/FQHC TO DEVELOP A TRAINING PROGRAM

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	2	$194
Nurse Practitioner/Physician Assistant	51	8	408
Total	....	10	602

Section 491.12(d) will also require that RHCs/FQHCs develop and maintain emergency preparedness training and testing programs that will be reviewed and updated at least annually. We believe that RHCs/FQHCs already review their emergency preparedness programs periodically. Therefore, we believe compliance with this requirement will constitute a usual and customary business practice for RHCs/FQHCs and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 491.12(d)(2) will require RHCs/FQHCs to participate in a full-scale exercise at least annually. They will also be required to participate in an additional testing exercise of their choice at least annually. RHCs/FQHCs will also be required to analyze their responses to and maintain documentation of drills, tabletop exercises, and emergency events, and revise their emergency plans, as needed. If an RHC or FQHC experienced an actual natural or man-made emergency that required activation of its emergency plan, it will be exempt from the requirement for a community or individual, facility-based full-scale exercise for 1 year following the onset of the actual event. However, for purposes of determining the burden for these requirements, we will assume that all RHCs/FQHCs will have to comply with all of these requirements.

The burden associated with complying with these requirements will be the resources the RHC or FQHC will need to develop the scenarios for the drill and exercise and the documentation necessary for analyzing and documenting their drills, tabletop exercises, as well as any emergency events.

Based on our experience with RHCs/FQHCs, we expect that most of the 11,500 RHCs/FQHCs already conduct some type of testing of their emergency preparedness plans and develop scenarios and documentation for their testing and emergency events. For example, FQHCs are expected to conduct some type of testing of their EMP at least annually (Emergency Management PIN, p. 7). However, we do not believe that all RHCs/FQHCs have the appropriate documentation for the testing exercises and emergency events or that they conduct both two testing exercises annually. Thus, we will analyze the burden associated with these requirements for all 11,500 RHCs/FQHCs.

Based on our experience with RHCs/FQHCs, we expect that the same individuals who are responsible for developing the RHC/FQHC's training and testing program will develop the scenarios for the drills and exercises and the accompanying documentation. We expect that the administrator and a registered nurse will be primarily involved in accomplishing these tasks. We estimate that for each RHC/FQHC to comply with the requirements in this section will require 5 burden hours at a cost of $347. Based on this estimate, for all 11,500 RHCs/FQHCs to comply with the requirements in this section will require 57,500 burden hours (5 burden hours for each RHC/FQHC × 11,500 RHCs/FQHCs) at a cost of $3,990,500 ($347 estimated cost for each RHC/FQHC × 11,500 RHC/FQHCs).

TABLE 120—TOTAL ESTIMATED COST FOR A RHC/FQHC TO CONDUCT TESTING

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$97	2	$194
Nurse Practitioner/Physician Assistant	51	3	153
Total	....	5	347

TABLE 121—BURDEN HOURS AND COST ESTIMATES FOR ALL 11,500 RHC/FQHCS TO COMPLY WITH THE ICRS CONTAINED IN § 491.12 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 491.12(a)(1) (RHCs)	0938–New	4,200	4,200	10	42,000	**	4,536,000	4,536,000
§ 491.12(a)(1) (FQHCs)	0938–New	7,300	7,300	5	36,500	**	3,796,000	3,796,000
§ 491.12(a)(1)–(4) (RHCs)	0938–New	4,200	4,200	14	58,800	**	5,791,800	5,791,800
§ 491(a)(1)–(4) (FQHCs)	0938–New	7,300	7,300	8	58,400	**	5,562,600	5,562,600
§ 491.12(b) (RHCs)	0938–New	4,200	4,200	12	50,400	**	6,224,400	6,224,400
§ 491.12(b) (FQHCs)	0938–New	7,300	7,300	8	58,400	**	6,803,600	6,803,600
§ 491.12(c) (RHCs)	0938–New	4,200	4,200	10	42,000	**	4,729,200	4,729,200
§ 491.12(c) (FQHCs)	0938–New	7,300	7,300	5	36,500	**	4,109,900	4,109,900
§ 491.12(d)(1)	0938–New	11,500	11,500	10	115,000	**	6,923,000	6,923,000
§ 491.12(d)(2)	0938–New	11,500	11,500	5	57,500	**	3,990,500	3,990,500
Totals	....	11,500	11,500	....	555,500	....	....	52,467,000

** The hourly labor cost is blended between the wages for multiple staffing levels.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 121.

S. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 494.62)

Section 494.62(a) will require dialysis facilities to develop and maintain emergency preparedness plans that will have to reviewed and updated at least annually. Section 494.62 will require that the plan include the elements set out at § 494.62(a)(1) through (4).

Section 494.62(a)(1) will require dialysis facilities to develop a documented, facility-based and community-based risk assessment utilizing an all-hazards approach. The risk assessment should address the medical and non-medical emergency events the facility could experience both within the facility and within the surrounding area. The dialysis facility will have to consider its location and geographical area; patient population, including, but not limited to, persons-at-risk; and the types of services the dialysis facility has the ability to provide in an emergency. The dialysis facility also will need to identify the measures it will need to take to ensure the continuity of its operations, including delegations of authority and succession plans.

The burden associated with this requirement will be the resources needed to perform a thorough risk assessment. The current CfCs already require dialysis facilities to implement processes and procedures to manage medical and nonmedical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failure, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area (§ 494.60(d)). Thus, to be in compliance with this CfC, we believe that all dialysis facilities will have already performed some type of risk assessment during the process of developing their emergency preparedness processes and procedures. However, these risk assessments may not be as thorough or address all of the elements required in § 494.62(a). For example, the current CfCs do not require dialysis facilities to plan for man-made disasters. Therefore, we believe that all dialysis facilities will have to conduct a thorough review of their current risk assessments and then perform the necessary tasks to ensure that their facilities' risk assessments complied with the requirements of this section.

Based on our experience with dialysis facilities, we expect that conducting the risk assessment will require the involvement of the dialysis facility's chief executive officer or administrator, medical director, nurse manager, social worker, and a patient care technician (PCT). We believe that all of these individuals will attend an initial meeting, review relevant sections of the current assessment, develop comments and recommendations for changes to the assessment, attend a follow-up meeting, perform a final review and approve the risk assessment. We believe that the administrator will probably coordinate the meetings, do an initial review of the current risk assessment, provide a critique of the risk assessment, offer suggested revisions, coordinate comments, develop the new risk assessment, and assure that the necessary parties approve the new risk assessment. We also believe that the administrator will probably spend more time reviewing and working on the risk assessment than the other individuals involved in performing the risk assessment. Thus, we estimate that complying with this requirement to conduct and develop a risk assessment will require 12 burden hours at a cost of $1,206. There are currently 6,648 dialysis facilities. Therefore, it will require an estimated 79,776 burden hours (12 burden hours for each dialysis facility × 6,648 dialysis facilities) for all dialysis facilities to comply with this requirement at a cost of $8,017,488 ($1,206 estimated cost for each dialysis facility × 6,648 dialysis facilities).

TABLE 122—TOTAL COST ESTIMATE FOR A DIALYSIS FACILITY TO CONDUCT A RISK ASSESSMENT

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$106	4	$424
Medical Director/Physician	207	2	414
Nurse Manager	94	2	188
Social Worker	51	2	102
Patient Care Dialysis Technician	39	2	78
Total		12	1,206

After conducting the risk assessment, each dialysis facility will then have to develop and maintain an emergency preparedness plan that the facility must evaluate and update at least annually. This emergency plan will have to comply with the requirements at § 494.62(a)(1) through (4).

Current CfCs already require dialysis facilities to have a plan to obtain emergency medical system assistance when needed and to evaluate at least annually the effectiveness of emergency and disaster plans and update them as necessary (§ 494.60(d)(4)). Thus, we expect that all dialysis facilities have some type of emergency preparedness or disaster plan. In addition, dialysis facilities must implement processes and procedures to manage medical and nonmedical emergencies that are likely to threaten the health or safety of the patients, the staff, or the public. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area (§ 494.60(d)). We expect that the facility will incorporate many, if not all, of these processes and procedures into its emergency preparedness plan. We expect that each dialysis facility has some type of emergency preparedness plan and that plan should already address many of these requirements. However, all of the dialysis facilities will have to review their current plans and compare them to the risk assessment they performed according to § 494.62(a)(1). The dialysis facility will then need to update, revise, and, in some cases, develop new sections to complete an emergency preparedness plan that addressed the risks identified in their risk assessment and the specific requirements contained in this section. The plan will also address how the dialysis facility will continue providing its essential services, which are the services that the dialysis facility will continue to provide despite an emergency. The dialysis facility will also need to review, revise, and, in some cases, develop delegations of authority or succession plans that the dialysis facility determined were necessary for the appropriate initiation and management of their emergency preparedness plan.

The burden associated with this requirement will be the time and effort necessary to develop the emergency preparedness plan. Based upon our experience with dialysis facilities, we expect that developing the emergency preparedness plan will require the involvement of the dialysis facility's chief executive officer or administrator, medical director, nurse manager, social worker, and a PCT. We believe that all of these individuals will probably have to attend an initial meeting, review relevant sections of the facility's current emergency preparedness or disaster plan(s), develop comments and recommendations for changes to the assessment, attend a follow-up meeting, and then perform a final review and approve the risk assessment. We believe that the administrator will probably coordinate the meetings, do an initial review of the current risk assessment, provide a critique of the risk assessment, offer suggested revisions, coordinate comments, develop the new risk assessment, and assure that the necessary parties approved the new risk assessment. We also believe that the administrator, medical director, and nurse manager will probably spend more time reviewing and working on the risk assessment than the other individuals involved in developing the plan. The social worker and PCT will likely just review the plan or relevant sections of it. In addition, since the medical director's responsibilities include participation in the development of patient care policies and procedures (42 CFR 494.150(c)), we expect that the medical director will be involved in the development of the emergency preparedness plan. This is less time than we estimate it will take for the risk assessment because dialysis facilities are currently required to have an emergency plan (§ 494.60(d)(4)). Based on this final rule, the dialysis facility will need to update, revise, and, in some cases, develop new sections to complete an emergency preparedness plan that addresses the risks identified in their risk assessment and the specific requirements contained in this regulation.

We estimate that complying with this requirement will require 10 burden hours at a cost of $1,116 for each dialysis facility. There are 6,648 dialysis facilities. Therefore, it will require an estimated 66,480 burden hours (10 burden hours for each dialysis facility × 6,648 dialysis facilities) to complete the plan at a cost of $7,419,168 ($1,116 estimated cost for each dialysis facility × 6,648 dialysis facilities).

TABLE 123—TOTAL COST ESTIMATE FOR A DIALYSIS FACILITY TO DEVELOP AN EMERGENCY PREPAREDNESS PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$106	4	$424
Medical Director/Physician	207	2	414
Nurse Manager	94	2	188
Social Worker	51	1	51
Patient Care Dialysis Technician	39	1	39
Total		10	1,116

Each dialysis facility will also be required to review and update its emergency preparedness plan at least annually. We believe that dialysis facilities already review their emergency preparedness plans periodically. The current CfCs already requires dialysis facilities to evaluate the effectiveness of their emergency and disaster plans and update them as necessary (42 CFR 494.60(d)(4)(ii)). Thus, we believe compliance with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 494.62(b) will require dialysis facilities to develop and implement emergency preparedness policies and procedures based on the emergency plan, the risk assessment, and communication plan as set forth in § 494.62(a), (a)(1), and (c), respectively. These emergencies will include, but will not be limited to, fire, equipment or power failures, care-related emergencies, water supply interruptions, and natural and man-made disasters that are likely to occur in the facility's geographical area. Dialysis facilities will also have to review and update these policies and procedures at least annually. The policies and procedures will be required to address, at a minimum, the requirements listed at § 494.62(b)(1) through (9).

We expect that all dialysis facilities have some emergency preparedness policies and procedures. The current CfCs at § 494.60(d) already require dialysis facilities to implement processes and procedures to manage medical and nonmedical emergencies that include, but not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. In addition, we expect that dialysis facilities already have procedures that will satisfy some of the requirements in this section. For example, each dialysis facility is already required at § 494.60(d)(4)(iii) to contact its local disaster management agency at least annually to ensure that such agency is aware of dialysis facility needs in the event of an emergency. However, all dialysis facilities will need to review their policies and procedures, assess whether their policies and procedures incorporated all of the necessary elements of their emergency preparedness program, and then, if necessary, take the appropriate steps to ensure that their policies and procedures encompassed these requirements.

The burden associated with the development of these emergency policies and procedures will be the time and effort necessary to comply with these requirements. We expect the administrator, medical director, and the nurse manager will be primarily involved with reviewing, revising, and if needed, developing any new policies and procedures that were needed. The remaining individuals will likely review the sections of the policies and procedures that directly affect their areas of expertise. Therefore, we estimate that complying with this requirement will require 10 burden hours at a cost of $1,116 for each dialysis facility. There are 6,648 dialysis facilities. Therefore, it will require an estimated 66,480 burden hours (10 burden hours for each dialysis facility × 6,648 dialysis facilities) to complete the plan at a cost of $7,419,168 ($1,116 estimated cost for each dialysis facility × 6,648 dialysis facilities).

TABLE 124—TOTAL COST ESTIMATE FOR A DIALYSIS FACILITY TO DEVELOP POLICIES AND PROCEDURES

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$106	4	$424
Medical Director/Physician	207	2	414
Nurse Manager	94	2	188
Social Worker	51	1	51
Patient Care Dialysis Technician	39	1	39
Total		10	1,116

The dialysis facility must also review and update its emergency preparedness policies and procedures at least annually. We believe that dialysis facilities already review their emergency preparedness policies and procedures periodically. In addition, the current CfCs already require (at 42 CFR 494.150(c)(1)) the medical director to participate in a periodic review of patient care policies and procedures. Thus, we believe compliance with this requirement will constitute a usual and customary business practice for dialysis facilities and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 494.62(c) will require dialysis facilities to develop and maintain an emergency preparedness communication plan that complied with both federal and state law. The dialysis facility must also review and update this plan at least annually. The communication plan must include the information listed at § 494.62(c)(1) through (7).

We expect that all dialysis facilities have some type of emergency preparedness communication plan. A communication plan will be an integral part of any emergency preparedness plan. Current CfCs already require dialysis facilities to have a written disaster plan (42 CFR 494.60(d)(4)). Thus, each dialysis facility should already have some of the contact information they will need to have in order to comply with this section. In addition, we expect that it is standard practice in the healthcare industry to have and maintain contact information for both staff and outside sources of assistance; alternate means of communications in case there is an interruption in phone service to the facility, such as cell phones or text-messaging devices; and a method for sharing information and medical documentation with other healthcare providers to ensure continuity of care for their patients. However, many dialysis facilities may not have formal, written emergency preparedness communication plans. Therefore, we expect that all dialysis facilities will need to review, update, and in some cases, develop new sections for their plans to ensure that those plans included all of the previously-described required elements in their emergency preparedness communication plan.

The burden associated with complying with this requirement will be the resources required to review and revise the dialysis facility's emergency preparedness communication plan to ensure that it complied with these requirements. Based upon our experience with dialysis facilities, we anticipate that satisfying these requirements will primarily require the involvement of the dialysis facility's administrator, medical director, and nurse manager. For each dialysis facility, we estimate that complying with this requirement will require 4 burden hours at a cost of $513. Therefore, for all of the dialysis facilities to comply with this requirement will require an estimated 26,592 burden hours (4 burden hours for each dialysis facility × 6,648 dialysis facilities) at a cost of $3,410,424 ($513 estimated cost for each dialysis facility × 6,648 dialysis facilities).

TABLE 125—TOTAL COST ESTIMATE FOR A DIALYSIS FACILITY TO DEVELOP A COMMUNICATION PLAN

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$106	2	$212
Medical Director/Physician	207	1	207
Nurse Manager	94	1	94
Total		4	513

Each dialysis facility will also have to review and update its emergency preparedness communication plan at least annually. For the purpose of determining the burden for this requirement, we will expect that dialysis facilities will review their emergency preparedness communication plans annually. We believe that all dialysis facilities have an administrator that will be primarily responsible for the day-to-day operation of the dialysis facility. This will include ensuring that all of the dialysis facility's policies, procedures, and plans were up-to-date and complied with the relevant federal, state, and local laws, regulations, and ordinances. We expect that the administrator will be responsible for periodically reviewing the dialysis facility's plans, policies, and procedures as part of his or her work responsibilities. Therefore, we expect that complying with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 494.62(d) will require dialysis facilities to develop and maintain emergency preparedness training, testing and patient orientation programs that will have to be evaluated and updated at least annually. The dialysis facility will have to comply with the requirements located at § 494.62(d)(1) through (3).

Section 494.62(d)(1) will require that dialysis facilities provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. Thereafter, the dialysis facility will have to provide emergency preparedness training at least annually.

Current CfCs already require dialysis facilities to provide training and orientation in emergency preparedness to the staff (§ 494.60(d)(1)) and provide appropriate orientation and training to patients in emergency preparedness (§ 494.60(d)(2)). In addition, the dialysis facility's patient instruction will have to include the same matters that are specified in the current CfCs (42 CFR 494.60(d)(2)). Thus, dialysis facilities should already have an emergency preparedness training program for new employees, as well as ongoing training for all their staff and patients. However, all dialysis facilities will need to review their current training programs and compare their contents to their updated emergency preparedness programs, that is, the risk assessment, emergency preparedness plan, policies and procedures, and communications plans that they developed in accordance with § 494.62(a) through (c). Dialysis facilities will then need to review, revise, and in some cases, develop new material for their training programs so that they complied with these requirements.

The burden associated with complying with this requirement will be the time and effort necessary to develop the required training program. We expect that complying with this requirement will require the involvement of the administrator, medical director, and the nurse manager. In fact, the medical director's responsibilities include, among other things, staff education and training (§ 494.150(b)). We estimate that it will require 7 burden hours for each dialysis facility to develop an emergency training program at a cost of $807. Therefore, it will require an estimated 46,536 burden hours (7 burden hours for each dialysis facility × 6,648 dialysis facilities) to comply with this requirement at a cost of $5,364,936 ($807 estimated cost for each dialysis facility × 6,648 dialysis facilities).

TABLE 126—TOTAL COST ESTIMATE FOR A DIALYSIS FACILITY TO DEVELOP A TRAINING PROGRAM

Position	Hourly wage	Burden hours	Cost estimate
Administrator	$106	3	$318
Medical Director/Physician	207	1	207
Nurse Manager	94	3	282
Total		7	807

The dialysis facility must also review and update its emergency preparedness training program at least annually. We believe that dialysis facilities already review their emergency preparedness training programs periodically. Therefore, we believe compliance with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 494.62(d)(2) requires dialysis facilities to participate in a full scale exercise at least annually. They will also be required to conduct one additional exercise of their choice at least annually. If the dialysis facility experienced an actual natural or man-made emergency that required activation of their emergency plan, the dialysis facility will be exempt from engaging in a full-scale exercise for 1 year following the onset of the actual event. Dialysis facilities will also be required to analyze their responses to and maintain document of all drills, tabletop exercises, and emergency events. To comply with this requirement, a dialysis facility will need to develop scenarios for each drill and exercise. A dialysis facility will also have to develop the documentation necessary for recording and analyzing the drills, tabletop exercises, and emergency events.

The current CfCs already require dialysis facilities to evaluate their emergency preparedness plan at least annually (42 CFR 494.60(d)(4)(ii)). Thus, we expect that all dialysis facilities are already conducting some type of tests to evaluate their emergency plans. Although the current CfCs do not specify the type of drill or test, dialysis facilities should have already been developing scenarios for testing their plans. Thus, we believe complying with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2).

Section 494.62(d)(3) will require dialysis facilities to provide appropriate orientation and training to patients, including the areas specified in § 494.62(d)(1). Section 494.62(d)(1) specifically will require that staff demonstrate knowledge of emergency procedures including the emergency information they must give to their patients. Thus, the burden associated with this section will already be included in the burden estimate for § 494.62(d)(1).

TABLE 127—BURDEN HOURS AND COST ESTIMATES FOR ALL 6,648 DIALYSIS FACILITIES TO COMPLY WITH THE ICRS CONTAINED IN § 494.62 CONDITION: EMERGENCY PREPAREDNESS

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§ 494.62(a)(1)	0938–New	6,648	6,648	12	79,776	**	8,017,488	8,017,488
§ 494.62(a)(2)–(4)	0938–New	6,648	6,648	10	66,480	**	7,419,168	7,419,168
§ 494.62(b)	0938–New	6,648	6,648	10	66,480	**	7,419,168	7,419,168
§ 494.62(c)	0938–New	6,648	6,648	4	26,592	**	3,410,424	3,410,424
§ 494.62(d)	0938–New	6,648	6,648	7	46,536	**	5,364,936	5,364,936
Totals		6,648	33,240		285,864			31,631,184

** The hourly labor cost is blended between the wages for multiple staffing levels.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 127.

T. Summary of Information Collection Burden

Based on the previous analysis, the burden for complying with all of the requirements in this final rule will be 3,089,505 burden hours at a cost of $279,680,069. Table 127 provides a summary of the ICR burden, for the hours and the costs, for each element of the requirements in this final rule for each provider and supplier type.

TABLE 128: TOTAL BURDEN HOUR ESTIMATES FOR ALL PROVIDERS AND SUPPLIERS TO COMPLY WITH THE ICRs CONTAINED IN THIS FINAL RULE: EMERGENCY PREPAREDNESS

Provider/Supplier	Risk Assessment Hours	Risk Assessment Costs ($)	Plan Development and Annual Review Hours	Plan Development and Annual Review Costs ($)	Development and Implementation of Policies and Procedures - Hours	Development and Implementation of Policies and Procedures – Cost ($)s	Communication Plan - Hours	Communication Plan – Costs ($)	Training and Exercise Hours	Training and Exercise Costs ($)	Total Hours	Total Costs ($)
RNCHIs	162	6,588	216	8,964	108	4.212	72	2.988	180	7,488	738	30.240
ASCs	39.952	3,810.422	54,934	4,679,378	44,946	3,580,698	19.976	1.613,062	60.335	4,711,615	220,143	18,395,175
Hospices	51,988	3,898,819	117,460	9,325,110	39,197	3,043,339	13,203	1.056,240	44,010	2,640,600	265,858	19,964,108
PRTFs	3,016	205,088	6,032	453,754	3,393	249,951	1,885	142.506	4,901	313,664	19,227	1,364,963
PACE	1.666	131,495	2,737	213,962	1,428	102,340	833	53.312	2.023	129,472	8,687	630,581
Hospitals	45,730	5,692,040	83,390	9,963,760	141,345	17,229,364	13,450	1.494,295	65,905	5,046,440	349,820	39,425,899
Transplant Centers*	0	0	0	0	0	0	0	0	0	0	0	0
LTC Facilities**	0	0	0	0	0	0	0	0	0	0	0	0
ICF/IIDs	49.898	4,097.709	56,133	4,677,750	56,133	4,677,750	37.422	3,118,500	68.607	4,752,594	268,191	21,324,303
HHAs	88.055	7,676.795	163,375	14,082,925	222,030	19,538,640	123.350	10.188.710	283.705	21,191,530	880,515	72,678,600
CORFs	1.640	148,010	2255	207,665	1,845	167,895	1.640	148.010	2.870	259,940	10,250	931,520
CAHs	14.985	1,493.505	25,974	2,558,439	16,178	1,573,171	12,033	1.111,047	25.854	2,439,196	95,024	9,175,358
Organizations	19.215	1,710.135	25,820	2,312,205	21,350	1,910,825	17.080	1,541,470	23.485	2,111,515	106,750	9,586,150
CMHCs	1.980	156,024	3,960	293,832	2,376	186,912	1.584	126.126	2.772	196,812	12,672	959,706
OPOs	580	69,020	1,624	188,906	4,640	539,052	812	90.828	2.610	227,476	10,266	1,115,282
RHCs/FQHCs	78.500	8,332.000	117,200	11,354,400	108,800	13,028,000	78.500	8,839,100	172.500	10,913,500	555,500	52,467,000
Dialysis Facilities	79.776	8,017.488	66,480	7,419,168	66,480	7,419,168	26.592	3,410,424	46.536	5,384,936	285,884	31,631,184
Totals	477.141	45,445,138	727,390	87,740,218	730,249	73,251,317	348.432	32,936,618	806.293	60,306,778	3,089,505	279,880,069

*We expect that since transplants are part of the hospital, they are usually involved in the hospital's programs as part of their normal business practices. Thus, compliance with these requirements will constitute a usual and customary business practice

**LTC Facilities OBRA '87 provides for a waiver of PRA requirements of the regulations implementing the OBRA '87 requirements.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn.: William Parham, (CMS–3178–F), Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: CMS Desk Officer, CMS–3178–F, Fax (202) 395–6974.

IV. Regulatory Impact Analysis

A. Statement of Need

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

In response to past terrorist attacks, natural disasters, and the subsequent national need to refine the nation's strategy to handle emergency situations, there continues to be a coordinated effort across federal agencies to establish a foundation for development and expansion of emergency preparedness systems. There are two Presidential Directives, HSPD–5 and HSPD–21, instructing agencies to coordinate their emergency preparedness activities with each other. Although these directives do not specifically require Medicare providers and suppliers to adopt measures, they have set the stage for what we expect from our providers and suppliers in regard to their roles in a more unified emergency preparedness system.

Homeland Security Presidential Directive (HSPD–5): Management of Domestic Incidents requires the Department of Homeland Security to develop and administer the National Incident Management System (NIMS).

Homeland Security Presidential Directive (HSPD–21) addresses public health and medical preparedness. The directive establishes a National Strategy for Public Health and Medical Preparedness (Strategy), which builds upon principles set forth in "Biodefense for the 21st Century" (April 2004), "National Strategy for Homeland Security" (October 2007), and the "National Strategy to Combat Weapons of Mass Destruction" (December 2002). The directive aims to transform our national approach to protecting the health of the American people against all disasters.

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995 Pub. L. 104–4), and Executive—Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). The total projected cost of this rule will be $373 million in the first year, and the subsequent projected annual cost will be approximately $25 million. We solicited and received comments on the proposed RIA. As such, we have presented our best estimate of the impact, including both costs and benefits, of this rule.

1. Disaster Data

Published reports after Hurricane Katrina reported that the Louisiana Attorney General investigated approximately 215 deaths that occurred in hospitals and nursing homes following Katrina. (Fink, Sheri (September 10, 2013). Five Days at Memorial: Life and Death in a Storm-Ravaged Hospital. New York: Crown Publishers. p. 360. ISBN 978–0–307–71896–9.) Since nearly all hospitals and nursing homes are certified to participate in the Medicare program, we estimate that at least a small percentage of these lives could be saved as a result of emergency preparedness measures in a single disaster of equal magnitude. Katrina is an extreme example of a natural disaster, so we also considered other more common disasters. The United States experiences numerous natural disasters annually, including, in particular, tornadoes and flooding. Based on data from the National Oceanic and Atmospheric Administration, the United States experiences an annual average of 56 fatalities as a result of tornadoes (*http://www.spc.noaa.gov/wcm/ustormaps/1981-2010-stateavgfatals.png*). On average, floods kill about 140 people each year (United States Department of the Interior, United States Geological Survey Fact Sheet "Flood Hazards—A National Threat" January, 2006, at *http://pubs.usgs.gov/fs/2006/3026/2006-3026.pdf*).

2. Benefits to Patients/Residents

It is commonly understood that healthcare facilities that do not have an emergency plan, develop policies and procedures, and train and exercise their staff are at a heightened risk for healthcare delivery and service disruptions. For instance, patients with ESRD have experienced problems accessing care and adverse outcomes during disasters. These patients are particularly at risk for having increased morbidity and mortality following disasters due to their dependence on regular life-maintaining dialysis treatments. Hurricane Katrina was particularly devastating for the dialysis-dependent population and led to the dialysis community, including facilities, recommending more integrated and better emergency planning, training and exercises in addition to other preparedness recommendations. One example was for dialysis facilities to implement early dialysis (an early treatment in advance of the storm's landfall) for notice weather events, such as hurricanes, snow storms, or other severe weather (Kenney, Robert J. "Emergency preparedness concepts for dialysis facilities: Reawakened after Hurricane Katrina." Clinical Journal of the American Society of Nephrology 2.4 (2007): 809–813 DOI: 10.2215/CJN.03971106). In order to implement early dialysis, particularly in moderate to large scale emergencies, facilities need to have an integrated emergency plan, policies and procedures, training and exercises. All of which are needed to better ensure that staff are able to rapidly activate and operate the facility emergency plan, prioritize and contact patients and transportation, and coordinate a surge in patient care coordination for both early and their regularly scheduled dialysis treatments.

Hurricane Sandy was predicted to be a severe storm many days in advance of its actual landfall. State health officials, in anticipation of its severity, encouraged dialysis facilities to dialyze patients ahead of schedule and rapidly activated the Kidney Community

Emergency Response (KCER) Coalition to provide additional assistance for coordinating notification and transportation services for patients, and to activate additional staff and resources to provide treatment at numerous facilities. Studies, following Hurricane Sandy, found regional variability in the receipt of early dialysis amongst the nearly 14,000 dialysis study patients. ASPR and CMS, using Medicare claims data, conducted the two studies to assess the impact of Hurricane Sandy on end-stage renal disease patients that require regular dialysis and to assess early dialysis treatment patterns and outcomes for those receiving it in the impacted areas. The first study identified a significant increase in the number of emergency department visits, hospitalizations, and patient death 30 days following the disaster and regional variability in patients receiving early dialysis prior to Hurricane Sandy's landfall. The second study found that the 60 percent of study patients that received early dialysis were found to have 20 percent lower odds of having an emergency department visit, 21 percent lower odds of a hospitalization in the week of the storm, and 28 percent lower odds of death 30 days after the storm. (Kelman J., Finne K., Bogdanov A., Worrall C., Margolis G., Rising K., MaCurdy T.E., Lurie N. Dialysis care and death following Hurricane Sandy. Am J Kidney Dis. 2015 Jan; 65(1):109–15. doi: 10.1053/j.ajkd.2014.07.005. Epub 2014 Aug 22. PubMed PMID: 25156306. and Lurie, N., Finne, K., Worrall, C., Jauregui, M., Thaweethai, T., Margolis, G., & Kelman, J. (2015). Early dialysis and adverse outcomes after Hurricane Sandy. Am J Kidney Dis., 66(3), 507–512.

Although we are unable to specifically quantify the number of lives saved as a result of this final rule, all of the data we have reviewed regarding emergency preparedness indicate that implementing the requirements in this final rule could have a significant impact on protecting the health and safety of individuals served by providers and suppliers that participate in the Medicare and Medicaid programs. The following cost analysis is based on "Guidelines for Regulatory Impact Analysis" (Robinson, L.A. and J.K. Hammitt. 2015, "Valuing Reductions in Risks of Fatal Illness: Implications of Recent Research." Health Economics. 25(8): 1039–1052) developed by Harvard University for the Assistant Secretary for Planning and Evaluation (ASPE). The Guidelines are not yet public, however based on the research that was published in Health Economics, we have provided the following cost analysis. In order to "break even" on the cost of this rule, that is, in order for the total costs of implementing this rule to equal the total benefits of doing so- this rule would need to save 11.5 lives per year for 5 years at a 7 percent discount rate and a value of $9 million per statistical life saved. It would take about 11 statistical lives saved per year for 5 years at a 3 percent discount rate for this final rule to break even. Therefore, we believe it is crucial for all providers and suppliers to have an emergency disaster plan that is integrated with other local, state and federal agencies to effectively address both natural and manmade disasters.

We believe that this final rule will be an economically significant regulatory action under section 3(f)(1) of Executive Order 12866, since it may lead to impacts of greater than $100 million in the first year following the rule's effective date.

This final rule will establish a regulatory framework with which Medicare- and Medicaid-participating providers and suppliers will have to comply to ensure that the varied providers and suppliers of healthcare are adequately prepared to respond to natural and man-made disasters.

3. The Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) (RFA) requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The Act defines a "small entity" as: (1) A proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a not-for-profit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of "small entity.") HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $11 million to $38.5 million in any 1 year. For purposes of the RFA, a majority of hospitals are considered small entities due to their non-profit status. Individuals and states are not included in the definition of a small entity. Since the cost associated with this final rule is less than $46,000 for hospitals and $4,000 for other entities, the Secretary has determined that this proposed will not have a significant economic impact on a substantial number of small entities."

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. Since the cost associated with this final rule is less than $46,000 for hospitals, this this proposed will not have a significant impact on the operations of a substantial number of small rural hospitals.

4. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that includes a federal mandate that could result in expenditure in any 1 year by state, local or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold level is approximately $146 million. This omnibus final rule contains mandates that will impose a one-time cost of approximately $373 million. Thus, we have assessed the various costs and benefits of this final rule. It is clear that a number of providers and suppliers will be affected by the implementation of this final rule and that a substantial number of those entities will be required to make changes in their operations. This final rule will not mandate any new requirements for state, local or tribal governments. For the private sector facilities, this regulatory impact section constitutes the analysis required under UMRA.

5. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it develops a final rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This final rule will not impose substantial direct requirement costs on state or local governments, preempt state law, or otherwise implicate federalism.

6. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

C. Anticipated Effects on Providers and Suppliers: General Provisions

This final rule will require each of the Medicare- and Medicaid-participating providers and suppliers discussed in previous sections to perform a risk analysis; establish an emergency preparedness plan, emergency preparedness policies and procedures, and an emergency preparedness communication plan; train staff in emergency preparedness, and test the emergency plan. The economic impact will differ between hospitals and the various other providers and suppliers, depending upon a variety of factors, including existing regulatory requirements and accreditation standards.

We discuss the economic impact for each provider and supplier type included in this final rule in the order in which they appear in the CFR. Most of the economic impact of this final rule will be due to the cost for providers and suppliers to comply with the information collection requirements. Thus, we discuss most of the economic impact under the Collection of Information Requirements section of this final rule. We provide a chart at the end of the RIA section of the total regulatory impact for each provider or supplier.

As stated in the ICR section of this final rule, we obtained all salary information from the May 2014 National Occupational Employment and Wage Estimates, United States by the Bureau of Labor Statistics (BLS) at *http://www.bls.gov/oes/current/oes_nat.htm* and calculated the added value of 100 percent for overhead and fringe benefits.

1. Subsistence Requirement

This final rule will require all inpatient providers to meet the subsistence needs of staff and patients, whether they evacuate or shelter in place, including, but not limited to, food, water, and supplies, alternate sources of energy to maintain temperatures to protect patient health and safety and for the safe and sanitary storage of such provisions.

Based on our experience, we expect inpatient providers to currently have food, water, and supplies, alternate sources of energy to provide electrical power, and the maintenance of temperatures for the safe and sanitary storage of such provisions as a routine measure to ensure against weather related and non-disaster power failures. Thus, we believe that this requirement is a usual and customary business practice for inpatient providers and we have not assigned any impact for this requirement.

Furthermore, we expect that most providers have agreements with their vendors to receive supplies within 24 to 48 hours in the event of an emergency, as well as arrangements with back-up vendors in the event that the disaster affects the primary vendor. We considered proposing a requirement that providers must keep a larger quantity of food and water on hand in the event of a disaster. However, we believe that a provider should have the flexibility to determine what is adequate based on the location and individual characteristics of the facility. While some providers may have the storage capacity to stockpile supplies that will last for a longer duration, other may not. Thus, we believe that to require such stockpiling will create an unnecessary economic impact on some healthcare providers.

We expect that when inpatient providers determine their supply needs, they will consider the possibility that volunteers, visitors, and individuals from the community may arrive at the facility to offer assistance or seek shelter.

Based on the previous factors, we have not estimated a cost for a stockpile of food and water.

2. Generator Location and Testing

We proposed to require hospitals, CAHs, and LTC facilities to test and maintain their emergency and standby power systems in such a way to ensure proper operation in the event they are needed. The 2012 edition of the Life Safety Code (LSC) of the NFPA® states that the alternate source of power (for example, generator) must be located in an appropriate area to minimize the possible damage resulting from disasters such as storms, floods, earthquakes, tornadoes, hurricanes, vandalism, sabotage and other material and equipment failures. Since hospitals, CAHs and LTC facilities are currently required to comply with the referenced LSC; we have not assigned any additional burden for this requirement.

In addition to the emergency power system inspection and testing requirements found in NFPA® 99 and NFPA® 110 and NFPA® 101, we proposed that hospitals test their emergency and stand-by-power systems for a minimum of 4 continuous hours every 12 months at 100 percent of the power load the hospital anticipates it will require during an emergency. We received the following public comment(s) on this requirement:

Comment: We received a large number of comments from individual hospitals as well as national and state organizations that expressed concern with the proposed requirement for hospitals, CAHs and LTC facilities to test their generators. Several commenters stated that there was not enough empirical data to support the proposed additional financial burden. Furthermore, they stated that there is no evidence that additional annual testing would result in more reliable generators and that their current testing schedule is sufficient. Several commenters stated that mandating additional testing would further burden already strained budgets and that the additional testing would cause unnecessary wear and tear on the equipment.

Response: We appreciate the commenters concerns on this issue. As we discussed previously in the preamble of this final rule, the purpose of the proposed change in the testing requirement was to minimize the issue of inoperative equipment in the event of a major disaster, such as what happened during the Sandy Super Storm. After carefully reviewing subsequent reports on the Sandy Super Storm (for example, the September, 2014 report of the Office of Inspector General (OIG) entitled, "Hospital Emergency Preparedness and Response During Super Storm Sandy; and the American Society for Healthcare Engineering (ASHE)), and the comments received on the proposed requirement, we believe that we do not have sufficient data to make the assumption that additional testing would ensure that the generators would withstand all disasters, regardless of the amount of testing conducted prior to an actual disaster. Therefore, we have decided against finalizing the proposed requirement for additional generator testing at this time. We expect facilities that have generators to continue to test their equipment based on current NFPA® codes (NFPA® 99 and NFPA® 110 and NFPA® 101) and manufacturer requirements.

3. Purchase of Communication Devices

We are finalizing our proposal to require providers and suppliers to develop and maintain a communication plan that includes the contact information for and a means for communicating with staff, federal, state, tribal, regional, and local emergency management entities. It is crucial for providers and suppliers to be aware of who to contact during an emergency situation and for them to have a means for communicating with the appropriate emergency management officials during an emergency or disaster. While we did not propose a specific mechanism for purposes of communicating during an emergency, we recognize the possibility that some providers and suppliers may need to purchase communication devices to meet the requirements of this final rule.

We anticipate that most providers and suppliers maintain updated information for staff as well as state and local officials as part of their typical business operations. We also expect that as a best practice, many providers and suppliers already utilize some type of communication system or device for purposes of communicating with their staff, physicians, volunteers, and other providers and suppliers during emergency situations. We want to reiterate that in addition to cellular phones, alternate communication devices may also include but are not limited to pagers, radio transceivers, various radio devices such as the National Oceanic and Atmospheric Administration's Weather Radio All Hazards, and Portable interconnected Voice over Internet Protocol (VoIP) services.

For purposes of the RIA, we assume that, at a minimum, those providers and suppliers without existing emergency preparedness requirements are mostly likely to be presented with the need to purchase communication devices to comply with the requirements of the communication plan in this final rule. Those provider and supplier types without any existing emergency preparedness requirements are CMHCs, OPOs, PRTFs, and outpatient hospices. As stated previously, this final rule will impact 17 different provider and supplier types. When taking into consideration all 17 provider and supplier types, this rule will have a combined impact on 72,315 entities (sum of the total number of provider and supplier entities). Those providers and supplier types without emergency preparedness requirements represent 6 percent of this total (4,622 total entities without existing emergency preparedness related requirements (198 CMHCs + 58 OPOs + 377 PRTFs + 3,989 outpatient hospices)/72,315 (sum of the total number of entities impacted by this regulation)). Therefore, we anticipate that, at a minimum 6 percent of the providers and suppliers impacted by this final rule will have the potential need to purchase communication devices to comply with the requirements of the final rule.

4. Use of Outside Consultants

We recognize that some of the provider and supplier types impacted by this final rule have more experience in the area of emergency preparedness than others. In particular, those provider and supplier types without existing emergency preparedness related requirements may find it useful to seek resources and guidance from outside consultants for purposes of complying with the requirements of this final rule. We note that we have not required providers and suppliers to hire outside consultants to develop their emergency preparedness programs, and we do not believe it will be necessary in most cases based on the free resources and information available to providers. Furthermore, in advance of hiring outside consultants, we encourage providers and suppliers to look to their local public health, emergency management agencies and local healthcare coalitions for assistance and guidance. Therefore, for purposes of the RIA we have not included a cost associated with the activity of hiring outside consultants, as we are unable to quantify with any degree of certainty the number of providers that may choose to use outside resources or the cost of such resources.

There are nearly 500 healthcare coalitions nationwide that providers and suppliers may seek to participate in, which currently include more than 24,000 healthcare facilities and community partners. In addition, providers and suppliers should leverage resources through their memberships with professional associations and non-government agencies, such as the Red Cross. Many non-government organizations and both national and local professional associations provide vetted emergency preparedness resources, materials and trainings. These organizations and healthcare coalitions also commonly conduct and support community-based exercises and encourage participation from other providers in their localities.

In addition, we note that there are several readily accessible, free, and expert-vetted, emergency preparedness resources that are available to providers and suppliers from government entities. First, providers and suppliers may access HHS' Office of the Assistant Secretary for Preparedness and Response (ASPR) Technical Resources Assistance Center Information Exchange (TRACIE) found at *https://asprtracie.hhs.gov/*. TRACIE can be used to locate sample plans, tools, templates, and training and exercise materials. TRACIE also provides access to expert technical assistance and an information-sharing exchange platform to assist the exchange of best practices, vetted tools, and information between public health, healthcare professionals, and many other emergency preparedness partners. TRACIE's technical assistance specialists can be reached Monday through Friday, 9 a.m. to 5 p.m. Eastern Standard Time, at 1–844–5–TRACIE or by email at *askasprtracie@hhs.gov*.

Providers and suppliers may also access the Centers for Disease Control and Prevention (CDC) Web site found at *http://www.cdc.gov/phpr/healthcare/planning.html*) for various tools and resources. In addition, there are many tools and free online training sessions related to emergency preparedness that are offered through FEMA's Emergency Management Institute (EMI) Web site found at *https://training.fema.gov/emi.aspx*.

Lastly, while we recognize that some providers may choose to seek some outside consulting assistance, we note that it is important that providers and suppliers develop their own plans to ensure that they truly understand their capabilities and can readily activate and implement their emergency and communication plans in the event of an emergency. Additional resources that can support provider and supplier preparedness are below:

- *HHS Response and Recovery Resources Compendium (http://www.phe.gov/emergency/hhscapabilities/Pages/default.aspx)*: HHS Response and Recovery Resources Compendium offers an easy-to-navigate, comprehensive, web-based repository of HHS resources and capabilities available to federal, state, tribal, territorial, and local agencies before, during, and after public health and medical incidents. The compendium spans 24 topics, including situational awareness and mass care and emergency assistance, and contains a list of the major HHS capabilities, products and services that support that each topic and information on accessing them.
- *DisasterLit (https://disasterlit.nlm.nih.gov/):* DisasterLit is a database of disaster medicine and public health resources selected from over 700 organizations available at no cost. These resources include guidelines, government and other technical documents, plans, videos, and training classes.
- *Public Service Announcements for Disasters:* Public Service Announcements (PSAs) provide a wide

variety of announcements on common issues in disaster preparedness, response and recovery. They can be used to help health communicators provide timely messages about what people can do to protect themselves, their families and their communities during disasters and emergencies. They are available in a wide variety of formats, including tweets, vines, podcasts, YouTube videos, broadcast scripts, and broadcast videos.

D. Condition of Participation: Emergency Preparedness for Religious Nonmedical Health Care Institutions (RNHCIs)

1. Training and Testing (§ 403.748(d))

We discuss the majority of the economic impact for this requirement in the ICR section, which is estimated at $30,240.

2. Testing (§ 403.748(d)(2))

Section 403.748(d)(2) will require RNHCIs to conduct a paper-based, tabletop exercise at least annually. RNHCIs must analyze their response and maintain documentation of all tabletop exercises, and emergency events, and revise their emergency plan as needed.

We expect that the cost associated with this requirement will be limited to the staff time needed to participate in the tabletop exercises. We estimate that approximately 4 hours of staff time will be required of the administrator and director of nursing, and 2 hours of staff time for the head of maintenance to coordinate facility evacuations and protocols for transporting residents to alternate sites. We believe that other staff members will be required to spend a minimal amount of time during these exercises and such staff time will be considered a part of regular on-going training for RNHCI staff. We estimate that it will require 10 hours of staff time for each of the 18 RNHCIs to conduct exercises at a cost of $476. Therefore, it will require an estimated total impact of $8,568 each year after the initial year for all RNHCIs to comply with § 403.748(d)(2). For the initial year, we estimate $38,808 as the total economic impact and cost estimates for all 18 RNHCIs to comply with the requirements in this final rule.

E. Condition for Coverage: Emergency Preparedness for Ambulatory Surgical Centers (ASCs)—Testing (§ 416.54(d)(2))

Section 416.54(d)(2) will require ASCs to participate in a full-scale exercise at least annually. ASCs also will be required to conduct one additional testing exercise of their choice at least annually. ASCs also will be required to maintain documentation of the exercise.

State, Tribal, Territorial, and local public health and medical systems comprise a critical infrastructure that is integral to providing the early recognition and response necessary for minimizing the effects of catastrophic public health and medical emergencies. Educating and training these clinical, laboratory, and public health professionals has been, and continues to be, a top priority for the federal Government. There are currently three programs at HHS addressing education and training in the area of public health emergency preparedness and response: The Centers for Public Health Preparedness (CPHP), the Bioterrorism Training and Curriculum Development Program (BTCDP), and National Laboratory Training Network (NLTN).

As discussed earlier in this preamble, ASCs can use these and other resources, such as tools offered by the Department of Homeland Security, to assist them in complying with this proposed requirement. Thus, we believe that the cost associated with this requirement will be limited to the staff time to participate in the community-wide and facility-wide trainings, and testing exercises. We believe that appreciable staff time will be required of the administrator and a registered nurse. We believe that other staff members will be required to spend a minimal amount of time during these exercises and the training will be considered as part of regular on-going training for ASC staff. We estimate that the administrator and a registered nurse will spend about 4 hours each on an annual basis to participate in the testing exercises. Thus, we anticipate that complying with this requirement will require 8 hours for an estimated cost of $724 for each of the 5,485 ASCs and a total cost estimate of $3,971,140 for all ASCs ($724 × 5,485 ASCs) each year after the first year. We estimate total costs for ASCs of $22,366,315 ($3,971,140 impact cost + $18,395,175ICR burden) in the first year of compliance, and $3,971,140, per year in subsequent years.

F. Condition of Participation: Emergency Preparedness for Hospices—Testing (§ 418.113(d)(2))

Section 418.113(d)(2)(i) through (iii) will require hospices to participate in testing exercises at least annually. We believe that the administrator will be responsible for participating in community-wide disaster drills and will be the primary person to organize any testing exercises with the assistance of one member of the IDG. We believe that the registered nurse will most likely represent the IDG during the testing exercises. While we expect that all staff will be involved in the testing exercises, we will consider their involvement as part of their regular staff training. However, for the purpose of this analysis we assume that the administrator will spend approximately 4 hours annually to participate in a full-scale exercise and one additional testing exercise of the facility's choice outside of their regular and ongoing training. We also assume that the registered nurse will spend 4 hours to participate in the testing exercises. Thus, we estimate that each hospice will spend $560. The total estimate for all hospices to comply with this requirement after the initial year will total $2,464,560 ($560 × 4,401 hospices). We estimate the total economic impact and cost estimates for all 4,401 hospices to comply with the requirements in this final rule for the initial year will be $22,428,668 ($2,464,560 impact cost + $19,964,108 ICR burden).

G. Emergency Preparedness for Psychiatric Residential Treatment Facilities (PRTFs)—Training and Testing (§ 441.184(d))

Section 441.184(d)(2)(i) through (iii) will require PRTFs to participate in a full-scale exercise and one additional exercise of their choice annually. We estimate that the cost associated with this requirement is the time that it will take key personnel to participate in the testing exercises. Furthermore, we estimate that the testing exercises will involve the administrator and registered nurse to spend about 4 hours each on an annual basis to participate. Thus, we anticipate that complying with this requirement will require 4 hours for the administrator (at a salary of $93 an hour) and 4 hours for the registered nurse (salary $64 an hour) at a combined estimated cost of $628 per facility. The total annual cost for all 377 PRTFs will be $236,756. The total cost for the first year to comply with the requirement will be $1,471,431 ($236,756 impact cost + $1,234,675 ICR burden).

H. Emergency Preparedness for Program for the All-Inclusive Care for the Elderly (PACE) Organizations—Training and Testing (§ 460.84(d))

Section 460.84(d)(2)(i) through (iii) will require PACE organizations to conduct a full-scale exercise and one additional testing exercise of their choice annually. Since PACE organizations are currently required to conduct a facility-wide drill annually, we are only estimating economic impact for the additional testing exercise. We expect that both the home-care coordinator and the quality-improvement nurse will each spend 1 hour to conduct the exercise. Thus, we estimate the economic impact hours to be 2 hours for each PACE organization at an estimated cost of $128 for each organization. The total annual cost for all PACE organizations is $15,232 ($128 × 119 providers). The total cost for all PACE organizations to comply with the requirements in the first year will be $645,904 ($15,323 impact cost + $630,581 ICR burden).

I. Condition of Participation: Emergency Preparedness for Hospitals

1. Medical Supplies (§ 482.15(b)(1))

We proposed that hospitals must maintain medical supplies. This regulation does not require sufficient supplies for a certain time frame, but other organizations do suggest standards. The American Hospital Association (AHA) recommends that individual hospitals have a 24-hour supply of pharmaceuticals and that they develop a list of required medical and surgical equipment and supplies. TJC standards require a hospital to have a 48 to 72 hour stockpile of medication and supplies.

The Department of Homeland Security (DHS) Act of 2002 established the Strategic National Stockpile (SNS) Program to work with governmental and non-governmental partners to upgrade the nation's public health capacity to respond to a national emergency. The SNS is a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications and medical supplies.

The SNS, and other federal agencies, *http://emergency.cdc.gov/stockpile/index.asp*, have plans to address the medical needs of an affected population in the event of a disaster. The SNS has large quantities of medicine and medical supplies to protect the American public if there is a public health emergency (for example, a terrorist attack, flu outbreak, or earthquake) severe enough to cause local supplies to run out. After federal and local authorities agree that the SNS is needed, medicines can be delivered to any state in the U.S. within 12 hours. Each state has plans to receive and distribute SNS medicine and medical supplies to local communities as quickly as possible. States have the discretion to decide where to distribute the supplies in the event of multiple events.

However, prudent emergency planning requires that some supplies be maintained in-hospital for immediate needs. The Federal Metropolitan Medical Response System (MMRS) guidelines call for MMRS communities to be self-sufficient for 48 hours. We encourage hospitals to work with stakeholders (state boards of pharmacy, pharmacy organizations, and public health organizations) for guidance and assistance in identifying medications they may need. Based on our experience with hospitals, we believe that they will have on hand a 2 to 3 day supply of medical supplies at the onset of a disaster. In the event of a prolonged emergency response, additional resources may be requested from state and federal agencies. CDC's Strategic National Stockpile (SNS), for example, has large quantities of medicine and medical supplies for a public health emergency that is severe enough to cause local supplies to run out and can deliver them to any state in the U.S. in time for them to be effective. Each state has plans to receive and distribute SNS medicine and medical supplies to local communities as quickly as possible. (*http://www.cdc.gov/phpr/stockpile/stockpile.html*).

Additional information regarding HHS' core capabilities to support public health and medical responses can be found in 2015 FEMA National Response Framework (see: *http://www.fema.gov/national-response-framework*) and more specifically within the Emergency Support Function #8 Public Health and Medical Annex that is located at *http://www.fema.gov/media-library-data/20130726-1914-25045-5673/final_esf_8_public_health_medical_20130501.pdf*. Therefore, based on the previous information, we are not assessing additional burden for medical supplies.

2. Training Program (§ 482.15(d)(1))

Section 482.15(d)(1) will require hospitals to develop and maintain an emergency preparedness training program and review and update it at least annually. Based on our experience with healthcare facilities, we expect that all healthcare facilities provide some type of training to all personnel, including those providing services under contract or arrangement and volunteers. Since such training is required for the TJC-accredited hospitals, the proposed requirements for developing an emergency preparedness-training program and the materials they plan to use in providing initial and on-going annual training will constitute a usual and customary business practice for TJC-accredited hospitals.

However, under this final rule, non TJC-accredited hospitals will need to review their existing training program and appropriately revise, update, or develop new sections and new material for their training program. The economic impact associated with this requirement is the staff time required for non-TJC accredited hospitals to review, update or develop a training program. We discuss the economic impact for this requirement in the ICR section.

3. Testing (§ 482.15(d)(2)(i) Through (iii))

Section 482.15(d)(2)(i) through (iii) will require hospitals to participate in or conduct a full-scale exercise and one additional testing exercise of their choice at least annually. State, tribal, territorial, and local public health and medical systems comprise a critical infrastructure that is integral in providing early recognition and response necessary for minimizing the effects of catastrophic public health and medical emergencies. Educating and training these clinical, laboratory, and public health professionals has been, and continues to be, a top priority for the federal government. There are currently three programs at HHS addressing education and training in the area of public health emergency preparedness and response. The programs are the Centers for Public Health Preparedness (CPHP), The Bioterrorism Training and Curriculum Development Program (BTCDP), and National Laboratory Training Network (NLTN). Hospitals can use these and other resources, such as tools offered by the DHS, to assist them in complying with this requirement. Thus, for non-TJC accredited hospitals, the costs associated with this requirement will be primarily due to the staff time needed to participate in the testing exercises. We believe that appreciable staff time will be required of the risk management director, facilities director, safety director, and security manager. We expect that other staff members will be required to spend a minimal amount of time during these exercises, which will be considered a part of regular on-going training for hospital staff. We estimate that the risk management director, facilities director, safety director and security manager will spend about 12 hours each on an annual basis to meet the proposed requirement.

Thus, we have estimated the economic impact for the 1,345 non-TJC accredited hospitals. We anticipate that complying with this requirement will require 48 hours for an estimate of $4,992 for each non TJC-accredited hospital. Therefore, it will cost all non TJC-accredited hospitals an estimated total cost of $6,714,240 ($4,992 per non

TJC-accredited hospital × 1,345 hospitals = $6,714,240).

Based on TJC's standards, the TJC-accredited hospitals are currently required to test their emergency operations plan twice a year. Therefore, for TJC-accredited hospitals to conduct testing exercises will constitute a usual and customary business practice and we will not include this activity in the economic impact analysis. We have estimated that the total economic impact of this final rule on hospitals will be $46,140,139 ($6,714,240 testing exercises impact cost + $39,425,899 ICR burden).

J. Condition of Participation: Emergency Preparedness for Transplant Centers

There is no additional economic impact to discuss in this section for transplant centers. All transplant centers are located within a hospital and, thus, will not have to stockpile supplies in an emergency or conduct testing exercises.

K. Emergency Preparedness for Long Term Care (LTC) Facilities (§ 483.73(b)

1. Subsistence (§ 483.73(b)(1))

Section 483.73(b)(1) will require LTC facilities to provide subsistence needs for staff and residents, whether they evacuate or shelter in place, including, but not limited to, food, water, and medical supplies alternate sources of energy for the provision of electrical power, and maintenance of temperatures for the safe and sanitary storage of such provisions.

As stated earlier in this section, each state has plans to receive and distribute SNS medicine and medical supplies to local communities as quickly as possible. The federal responsibility ceases at the delivery of the push-packs to state-designated airports. It is then the responsibility of the state to break down and transport the components of the push-pack to the affected community. It is also at the state's discretion where to deliver push-pack material in the event of multiple events.

We expect that a 1- to 2-day supply will be sufficient because various national agencies with stockpiles of medicine, medical supplies, food and water can be mobilized within 12 hours and supplies can be replenished or provided within 48 hours. Thus, for the sake of this impact analysis, we assume that, at a minimum, a LTC facility will have a 2-day supply of food and potable water for the patients and staff at the onset of a disaster and will not assign a cost to this requirement.

We encourage LTC facilities to work with stakeholders (State Boards of Pharmacy, pharmacy organizations, and public health organizations) for guidance and assistance in identifying medications that may be needed and plan to provide access to all healthcare partners during an event.

2. Training and Testing (§ 483.73(d))

Section 483.73(d)(2)(i) through (iii) will require LTC facilities to participate in or conduct a full-scale exercise and one additional testing exercise of their choice at least annually. The current requirements for LTC facilities already mandate that these facilities periodically review their procedures with existing staff, and carry out unannounced staff drills (§ 483.75(m)(2)). Thus, we expect that complying with the requirement for annual testing of their emergency plan will constitute a minimal economic impact, if any.

Therefore, the cost of this final rule for all LTC Facilities will be limited to the ICR burden of $68,808,717 as discussed in the COI section.

L. Condition of Participation: Emergency Preparedness for Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs/IID)—Testing (§ 483.475(d)(2))

Section 483.475(d)(2)(i) through (iii) will require ICFs/IID to participate in or conduct a full scale exercise and one additional testing exercise of their choice at least annually. The current ICF/IID CoPs require them to conduct evacuation drills at least quarterly for each shift and under varied conditions to evaluate the effectiveness of emergency and disaster plans and procedures (§ 483.470(i) and (i)(iii)). In addition, ICFs/IID must evacuate clients during at least one drill each year on each shift, file a report and evaluation on each evacuation drill and investigate all problems with evacuation drills, including accidents, and take corrective action (§ 483.470(i)(2)). Since all 6,237 ICFs/IID already conduct quarterly drills, we estimate a small additional burden to cover the added complexities of the rule. Specifically, the rule would require the administrator and the registered nurse each to spend an additional hour to participate in testing programs for their facility. Thus, we estimate that the additional cost for each ICF/IID to comply with this requirement would be $157 for each facility. The total estimate for all facilities to comply with this requirement is $979,209 ($157 × 6,237 facilities = $979,209). We estimate the total cost will be $22,303,512 ($21,324,303 ICR burden + $979,209 impact cost).

M. Condition of Participation: Emergency Preparedness for Home Health Agencies (HHAs)—Training and Testing (§ 484.22(d))

We discuss the majority of the economic impact for this requirement in the COI section which is estimated to be $72,678,600.

Section 484.22(d)(2)(i) through (iii) will require HHAs to participate in a full-scale exercise and one additional testing exercise of their choice at least annually. We also require the HHA to maintain documentation of the testing exercises.

There are currently three programs at HHS addressing education and training in the area of public health emergency preparedness and response: The Centers for Public Health Preparedness (CPHP), the Bioterrorism Training and Curriculum Development Program (BTCDP), and National Laboratory Training Network (NLTN). HHAs can use these and other resources, such as tools offered by the Department of Homeland Security, to assist them in complying with this requirement. HHS' Office of the Assistant Secretary for Preparedness and Response (ASPR) and HHS's Centers for Disease Control and Prevention (CDC) also provides numerous tools and resources on their Web site (see *http://www.cdc.gov/phpr/healthcare/planning.html*) in addition to the many tools and free online training sessions that are offered on FEMA's Emergency Management Institute (EMI) Web site (*https://training.fema.gov/emi.aspx*). Thus, we believe that the cost associated with this requirement will be limited to the staff time to participate in the community-wide and facility-wide trainings, and testing exercises. We believe that appreciable staff time will be required of the administrator and director of training. We believe that other staff members will be required to spend a minimal amount of time during these exercises and the training will be considered as part of regular on-going training for HHA staff. We estimate that the administrator will spend about 2 hours to participate in the testing exercises. We also estimate that the director of training will spend a total of 3 hours on an annual basis to participate in the testing exercises. All TJC accredited HHAs are required annually to test their emergency management program by conducting drills and documenting their results. Thus, we anticipate that only non-TJC accredited HHAs will need to comply with this requirement. We anticipate that it will require 5 hours for each of the 8,005 non-JC-accredited HHAs, with an estimated cost of $2,945,840. Therefore, the total economic impact of this rule on HHAs will be $75,624,440 ($2,945,840 impact cost + $72,678,600 ICR burden).

N. Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities (CORFs)—Training and Testing (§ 485.68(d)(2)(i) Through (iii))

Section 485.68(d)(2)(i) through (iii) will require CORFs to participate in or conduct a full-scale exercise and one additional exercise of their choice at least annually and document the testing exercises. To comply with this requirement, a CORF will need to develop a specific scenario for each exercise.

The current CoPs require CORFs to provide ongoing drills for all personnel associated with the facility in all aspects of disaster preparedness (§ 485.64(b)(1)). Thus, for the purpose of this analysis, we believe that CORFs will incur minimal or no additional cost to comply with this requirement. Thus, we estimate the cost for all 205 CORFs to comply with this requirement will be limited to the ICR burden of $931,520 discussed in the COI section.

O. Condition of Participation: Emergency Preparedness for Critical Access Hospitals (CAHs) Training and Testing (§ 485.625(d)(2))

Section 485.625(d)(2)(i) through (iii) will require CAHs to conduct two annual testing exercises. Accredited CAHs are currently required to conduct such drills and exercises (See COI section for detailed discussion regarding our review of accrediting organizations). Although we believe that non-accredited CAHs are currently participating in such drills and exercises, we are not convinced that it is at the level that will be required under this final rule. Thus, we will analyze the economic impact for these requirements for the 892 non-accredited CAHs. As discussed earlier in the preamble, CAHs will have access to various training resources and emergency preparedness initiatives to use in complying with this requirement. Thus, we believe that the cost associated with this requirement will be limited to staff time to participate in the community-wide and facility-wide trainings, and testing exercises. We believe that appreciable staff time will be required of the administrator, facilities director, director of nursing and nursing education coordinator. We believe that other staff members will be required to spend a minimal amount of time during these exercises that will be considered as part of regular on-going training for hospital staff. We estimate that the administrator (for 7 hours), facilities director (for 6 hours), and the director of nursing (for 7 hours) will spend approximately a total of 20 hours on an annual basis to participate in the testing exercises. Thus, we anticipate that complying with this requirement will require 20 hours for an estimated cost of $1,856 for each of the 892 non-accredited CAHs. Therefore, for all non-accredited CAHs to comply with this requirement, it will require 17,800 total economic impact hours (20 economic impact hours per non-accredited CAH × 892 non-accredited CAH) at an estimated total cost of $1,655,552 ($1,856 × 892). Therefore, the total economic impact of this rule on CAHs will be $10,830,910 ($1,655,552 testing exercises impact cost + $9,175,358 ICR burden).

P. Condition of Participation: Emergency Preparedness for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology ("Organizations")—Testing (§ 485.727(d)(2)(i) Through (iii))

Current CoPs require these organizations to ensure that employees are trained in all aspects of preparedness for any disaster. They are also required to have ongoing drills and exercises to test their disaster plan. Rehabilitation Agencies will need to review their current activities and make minor adjustment to ensure that they comply with the new requirement. Therefore, we expect that the economic impact to comply with this requirement will be minimal, if any. Therefore, the total economic impact of this rule on these organizations will be limited to the estimated ICR burden of $9,586,150.

Q. Condition of Participation: Emergency Preparedness for Community Mental Health Centers (CMHCs)—Training and Testing (§ 485.920(d))

Section 485.920(d)(2) will require CMHCs to participate in or conduct a full-scale exercise and one additional testing exercise of their choice at least annually. We estimate that to comply with the requirement to participate in these testing exercises annually will primarily require the involvement of the administrator and a registered nurse. We estimate that the administrator will spend approximately 5 hours to participate in these testing exercises. We also estimate that a nurse will spend about 3 hours on an annual basis to participate in the testing exercises. Thus, we anticipate that complying with this requirement will require 8 hours for each CMHC at an estimated cost of $683 for each facility. The economic impact for all 198 CMHCs will be 135,234 ($683 × 198 CMHCs). Therefore, the total economic impact of this final rule on CMHCs will be $1,094,940 ($135,234 impact cost + $959,706 ICR burden).

R. Conditions of Participation: Emergency Preparedness for Organ Procurement Organizations (OPOs)—Training and Testing (§ 486.360(d)(2)(i) Through (iii))

The OPO CfCs do not currently contain a requirement for OPOs to conduct testing exercises. We estimate that these tasks will require the quality assessment and performance improvement (QAPI) director and the education coordinator to each spend 1 hour to participate in the testing exercises. Thus, the total annual economic impact hours for each OPO will be 2 hours. The total cost will be $188 for a (QAPI coordinator hourly salary and the Education Coordinator to participate). The economic impact for all OPOs will be 188 (2 impact hours × 58 OPOs) total economic impact hours at an estimated cost of $10,904 (188 × 58 OPOs). Therefore, the total economic impact of this rule on OPOs will be $1,126,186 ($10,904 impact cost + $1,115,282 ICR burden).

S. Emergency Preparedness: Conditions for Certification for Rural Health Clinics (RHCs) and Conditions for Coverage for Federally Qualified Health Clinics (FQHCs)

1. Training and Testing (§ 491.12 (d))

We expect RHCs and FQHCs to participate in their local and state emergency plans and training drills to identify local and regional disaster centers that could provide shelter during an emergency.

We proposed that an RHC/FQHC must review and update its emergency preparedness policies and procedures at least annually. For purposes of determining the economic impact for this requirement, we expect that RHCs/FQHCs will review their emergency preparedness policies and procedures annually. Based on our experience with Medicare providers and suppliers, healthcare facilities have a compliance officer or other staff member who reviews the facility's program periodically to ensure that it complies with all relevant federal, state, and local laws, regulations, and ordinances. We believe that complying with the requirement for an annual review of the emergency preparedness policies and procedures will constitute a minimal economic impact, if any.

2. Testing (§ 491.12(d)(2)(i) Through (iii))

Section 491.12(d)(2)(i) through (iii) will require RHCs/FQHCs to participate in a full-scale exercise and one additional testing exercise of their choice at least annually. We have stated previously that FQHCs are currently required to conduct annual drills. We believe that for FQHCs to comply with these requirements will constitute a minimal economic impact, if any. Thus, we are estimating the economic impact for RHCs to comply with these requirements to conduct testing exercises. We estimate that a RHCs administrator will spend 4 hours annually to participate in the exercises. Also, we estimate that a nurse coordinator (registered nurse) will each spend 4 hours on an annual basis to participate in the testing exercises. Thus, we anticipate that complying with this requirement will require 8 hours for each RHC for an estimated cost of $672 per facility. The total annual cost for 4,200 RHCs will be $4,905,600. Therefore, the total economic impact of this rule on RHCs/FQHCs will be $57,372,600 ($4,905,600 impact cost + $52,467,000 ICR burden).

T. Condition of Participation: Emergency Preparedness for End-Stage Renal Disease Facilities (Dialysis Facilities)—Testing (§ 494.62(d)(2)(i) Through (iv))

Section 494.62(d)(2) will require dialysis facilities to participate in or conduct a full-scale exercise and one additional testing exercise of their choice at least annually. The current CfCs already require dialysis facilities to evaluate their emergency preparedness plan at least annually (§ 494.60(d)(4)(ii)). Thus, we expect that all dialysis facilities are already conducting some type of tests to evaluate their emergency plans. Although the current CfCs do not specify the type of drill or test, we believe that dialysis facilities are currently participating in community or facility-wide drills. Therefore, for the purpose of this impact analysis, we estimate that dialysis facilities will need to add the additional testing exercise of their choice to their emergency preparedness activities. We estimate that it will require 1 hour each for the administrator (hourly wage of $106.00) and the nurse manager (hourly wage of $94.00) to conduct the additional exercise. We estimate the total cost to be $200 for each facility, with a total economic impact of $1,329,600 ($200 × 6,648 facilities). Therefore, the total economic impact of this rule on ESRD facilities will be $32,960,784 ($1,329,600 impact cost + $31,631,184 ICR burden).

U. Summary of the Total Costs

The following is a summary of the total providers and the annual cost estimates for all providers to comply with the requirements in this rule.

TABLE 129—TOTAL ANNUAL COST TO PARTICIPATE IN DISASTER DRILLS ACROSS THE PROVIDERS/SUPPLIERS

Facility	Number of participants	Total cost (in millions $)
RNHCI	18	0.01
ASC	5,485	3.97
Hospices	4,401	2.46
PRTFs	377	0.24
PACE	119	0.02
Hospital	4,793	6.71
HHAs	12,335	2.95
CAHs	1,337	1.66
CMHCs	198	0.14
OPOs	58	0.01
RHCs & FQHCs	11,500	4.91
ESRD	6,648	1.33
Total	47,269	25.37

Based upon the ICR and RIA analyses, it will require 62,968 providers and suppliers covered by this emergency preparedness final rule to comply with all of its requirements with an estimated total first-year cost of $373 million. After the initial cost of $373 million associated with conducting a risk assessment and developing an EP plan, the annual cost for the total providers and suppliers to test their plans and train staff will be $25 million.

TABLE 130—TOTAL ESTIMATED COST FROM ICR AND RIA TO COMPLY WITH THE REQUIREMENTS CONTAINED IN THIS FINAL RULE

Facility	Number of participants	Total cost in year 1 (in millions of $)	Total cost in year 2 and subsequent years (in millions of $)
RNHCI	18	0.04	0.01
ASC	5,485	22.37	3.97
Hospices	4,401	22.43	2.46
PRTFs	377	1.47	0.24
PACE	119	0.65	0.02
Hospital	4,793	46.14	6.71
Transplant Center	770	0.00	0.00
LTC	15,699	68.81	0.00
ICF/IID	6,237	22.30	0.98

TABLE 130—TOTAL ESTIMATED COST FROM ICR AND RIA TO COMPLY WITH THE REQUIREMENTS CONTAINED IN THIS FINAL RULE—Continued

Facility	Number of participants	Total cost in year 1 (in millions of $)	Total cost in year 2 and subsequent years (in millions of $)
HHAs	12,335	75.62	2.95
CORFs	205	0.93	0.00
CAHs	1,337	10.83	1.66
Organizations	2,135	9.59	0.00
CMHCs	198	1.09	0.14
OPOs	58	1.13	0.01
RHCs & FQHCs	11,500	57.37	4.91
ESRD Facilities	6,648	34.29	1.33
Total	72,315	$373	$25

The previous summaries include only the upfront and routine costs associated with emergency risk assessment, development and updating of policies and procedures, development and maintenance of communication plans, disaster training and testing, and generator testing (as specified). If these preparations are effective, they will lead to increased amounts of life-saving and morbidity-reducing activities during emergency events. These activities impose cost on society; for example, if complying with this final rule's requirements allows an ESRD facility to remain open during and immediately after a natural disaster, there will be associated increases in provision of dialysis services, thus entailing labor, material and other costs. As discussed in the next section (''Benefits of the Final Rule''), it is difficult to predict how disaster responses will be different in the presence of this final rule than in its absence, so we have been unable to quantify the portion of costs that will be incurred during emergencies.

V. Benefits of the Final Rule

The Presidential Policy Directive/PPD–8 is aimed at strengthening the security and resilience of the United States through systematic preparation for the threats that pose the greatest risk to the security of the nation, including acts of terrorism, cyber-attacks, pandemics, and catastrophic natural disasters. (*https://www.dhs.gov/presidential-policy-directive-8-national-preparedness*). ''Having systems in place to provide better treatment for disaster survivors and improved public health for our communities also leads to better health outcomes on a day-to-day basis.'' *http://www.phe.gov/Preparedness/planning/hpp/Pages/funding.aspx.* As frontline entities in response to mass casualty incidents, hospitals and other healthcare providers such as health centers, rural hospitals and private physicians will be looked to for minimizing the loss of life and permanent disabilities. Hospitals and other healthcare provider organizations must be able to work not only inside their own walls, but also as a team during an emergency to respond efficiently. Based on our experience, hospitals currently, either through experience or empirical evidence, gain knowledge that causes them to become very adept at adjusting their systems to respond in an emergency. Because we live under the threat of mass casualties occurring at anytime and anywhere with consequences that may be different than the day-to-day occurrences, the healthcare system must be prepared to respond to these events by working as a team or community system.

This final rule serves to help ensure continuity of care and service delivery for those that depend on the healthcare system both daily and in the event of a disaster by requiring providers and suppliers to adequately plan for and respond to both natural and man-made disasters. The devastation of the Gulf Coast by Hurricane Katrina is one of the most horrific disasters in our nation's history. In those chaotic early days following the disaster in the greater New Orleans area, hundreds of thousands of people were adversely impacted, and healthcare services were not available for many who needed them. Rudowitz, Robin, Diane Rowland, and Adele Shartzer. ''Health care in New Orleans before and after Hurricane Katrina.'' Health Affairs 25.5(2006): w393–w406. . There is no reason to believe that future disasters might not be as large or larger. In the event of such disasters, vulnerable populations are at greatest risk for negative consequences from healthcare disruptions. Individuals requiring mental health treatments are another at-risk population that can be adversely impacted by healthcare disruptions following an emergency or disaster. A 2008 study concluded that many Hurricane Katrina survivors with mental disorders experienced unmet treatment needs, including frequent disruptions of existing care and widespread failure to initiate treatment for new-onset disorders (Wang, P.S., et al. ''Disruption of Existing Mental Health Treatments and Failure to Initiate New Treatment After Hurricane Katrina. American Journal of Psychiatry, 165(1), 34–41)'' (2006).

Hospital closures during Sandy resulted in up to a 25 percent increase in emergency department visits at numerous centers in New York and a 70 percent increase in ambulance traffic. Not only do vulnerable populations experience disruptions in care, they may also incur increased costs for care, especially when those who require ongoing medical treatment during disasters are required to visit emergency departments for treatment and or hospitalization. (Absorbing citywide patient surge during Hurricane Sandy: a case study in accommodating multiple hospital evacuations.) (Ann Emerg Med. 2014 Jul ;64(1):66–73.e1. doi: 10.1016/j.annemergmed.2013.12.010. Epub 2014 Jan 10.); (Howard D, Zhang R, Huang Y, Kutner N. Hospitalization rates among dialysis patients during Hurricane Katrina. Prehosp Disaster Med. 2012;27(4):1–5.).)

Emergency department visits incur a copay for most beneficiaries. Similar costs are also incurred by patients for hospitalizations. The literature shows that natural catastrophes disproportionately affect ill and socioeconomically disadvantaged populations that are most at risk (Abdel-Kader K, Unrah ML. Disaster and end-stage renal disease: targeting vulnerable patients for improved outcomes. Kidney Int. 2009;75:1131–1133; Zoraster R, Vanholder R, Sever MS. Disaster management of chronic dialysis patients. Am J Disaster Med. 2007;2(2):96–106; and Redlener I, Reilly M. Lessons from Sandy—Preparing Health Systems for Future Disasters. N ENGL J MED. 367;24:2269–2271).

We know that advance planning improves disaster response. In 2007, *Modern Healthcare* reported on a healthcare system's response to encroaching wildfires in California. Staff from a San Diego hospital and adjacent nursing facility transported 202 patients and ensured all patients were out of harm's way. The facilities were ready because of protocols and evacuation drills instituted after a prior event that allowed them to be prepared (Vesely, R. (2007). Wildfires worry hospitals. Modern Healthcare, 37(43), 16).

Therefore, we believe that it is essential to require providers and suppliers to conduct a risk assessment, to develop an emergency preparedness plan based on the assessment, and to comply with the other requirements we propose to minimize the disruption of services for the community and ensure continuity of care in the event of a disaster. As noted previously, we have varied our requirements by provider type and understand that the degree of vulnerability of patients in a disaster will vary according to provider type. For example, patients with scheduled outpatient appointments such as someone coming in for speech therapy or routine clinic services is likely more self-reliant in a disaster than someone in a hospital ICU or someone who is homebound and receiving services from an HHA.

Overall, we believe that this final rule will reduce the risk of mortality and morbidity associated with disasters. While New Orleans has a unique location, below sea level, everywhere in the United States is vulnerable to weather emergencies and other potential natural or manmade disasters. A recent report, "In the path of the Storm" (*http://www.environmentamerica.org/reports/ame/path-storm*) that studied FEMA disaster declaration and other data from 2007 through 2012 found that federally declared weather-related disasters in the United States have taken place in every state except for one, and affected every county in 18 states and the District of Columbia. It also found that more than 19 million Americans live in counties that have an average of one or more weather-related disasters per year since the beginning of 2007." (*http://www.environmentamerica.org/reports/ame/path-storm*). Sometimes, these disasters can have adverse impacts on the health of communities. For example, more than 15,000 dialysis patients located within the State of New Jersey and New York City boroughs were exposed to the impacts of Hurricane Sandy that resulted in significant treatment disruptions. (Kelman, Jeffrey, et al. "Dialysis care and death following Hurricane Sandy." American Journal of Kidney Diseases 65.1 (2015): 109–115).

The White House, in July 2014, also released a report titled "The Health Impacts of Climate Change on Americans" (*https://www.whitehouse.gov/sites/default/files/docs/the_health_impacts_of_climate_change_on_americans_final.pdf*). The report states that extreme heat exposures for the period of 1999–2009 caused more than 7,800 deaths in the U.S. As climate change progresses, extreme heat will "also increase hospital admissions for cardiovascular, respiratory, cerebrovascular diseases and deaths from heat stroke and other related conditions (*https://health2016.globalchange.gov.*" On April 4, 2016, The White House also published the Climate and Health Assessment Report" (*https://www.whitehouse.gov/the-press-office/2016/04/04/fact-sheet-what-climate-change-means-your-health-and-family* (actual report: *https://health2016.globalchange.gov/*) that provides a comprehensive, evidenced-based, and where possible quantitative estimation of observed and projected public health impacts related to climate change in the U.S. that will also inform state, and local governments and communities on climate change risks. (see *https://www.whitehouse.gov/sites/default/files/docs/the_health_impacts_of_climate_change_on_americans_final.pdf* and *http://www.globalchange.gov/health-assessment.*

According to the CDC, changing climate is linked to increases in a wide range of non-communicable and infectious diseases. There are complex ways in which climatic factors (like temperature, humidity, precipitation, extreme weather events, and sea-level rise) can directly or indirectly affect the prevalence of disease. Identification of communities and places vulnerable to these changes can help healthcare providers prepare to work with health departments as they assess such health vulnerabilities associated with climate change and prevent associated adverse health impacts. CDC has developed the Building Resilience Against Climate Effects (BRACE) framework to help health departments prepare for and respond to climate change. Additional information can be found at: *http://www.cdc.gov/climateandhealth/brace.htm.*

While we are unable to quantify the number of lives that could be saved by emergency planning and execution, Table 131 provides the number of Medicare FFS beneficiaries receiving services from some of the provider types affected by this final rule during the month of May 2016. We are unable to provide volume data for those patients in Medicare Advantage plans or the Medicaid population. However, one could assume the May 2016 summary is representative of an average month during the year. In the event of a disaster, a portion of the fee-for-service patients represented in Table 131 could be at risk; therefore, we could assume that they could benefit from the additional emergency preparedness measures in this final rule.

TABLE 131—NUMBER OF MEDICARE FFS PATIENTS WHO RECEIVED SERVICES MAY 2016

Provider type	Number of FFS patients
Children's hospital	3,731
Community Mental Health Center	96,583
Comprehensive Outpatient Rehabilitation Facility	3,673
Critical Access Hospital	685,912
HHA	1,043,827
Hospice	322,565
Hospital based chronic renal disease facility	7,700
Long-term hospital	18,842
Non hospital renal disease treatment center	280,189
ORD demonstration project hospital	3,078

TABLE 131—NUMBER OF MEDICARE FFS PATIENTS WHO RECEIVED SERVICES MAY 2016—Continued

Provider type	Number of FFS patients
Psychiatric hospital	37,975
Rehabilitation hospital	45,995
Religious Nonmedical Health Care Institution	29
Renal disease treatment center	7,221
Reserved number	68,734
Rural health clinic (free standing)	208,942
Rural health clinic (provider based)	325,051
Short-term hospital	7,104,897
Skilled Nursing Facility	539,061

Note: In May 2016 there were 9,283,219 distinct patients.

Benefits from effective disaster planning will not only accrue to individuals requiring healthcare services. Healthcare facilities themselves may benefit from improved ability to maintain or resume delivering services. After Hurricane Katrina, 94 dialysis facilities closed for at least 1 week. More than a month after super storm Sandy devastated flood-prone communities in New Jersey and New York, five hospitals were unable to admit patients because of damage that destroyed electrical systems, flooded emergency and exam rooms and crippled elevators. Following Hurricane Sandy, $180 million of the $810 million damages reported by the New York City Health and Hospitals Corporation was due to lost revenue. Lost revenue from Long Beach Medical Center hospital and nursing home was estimated at $1.85 million a week after closing due to damage from Hurricane Sandy. *http://www.modernhealthcare.com/article/20121208/MAGAZINE/312089991#ixzz2adUDjFIE?trk=tynt.*

Finally, taxpayers and insurance companies may benefit from effective emergency preparedness. After Hurricane Ike, it was estimated that the cost to Medicare for ESRD patients presenting to the ED for dialysis instead of their usual facility was, on average, $6,997 per visit. Those ESRD patients who did not require dialysis were billed $482 on average (McGinley et al, 2012). The usual cost for these patients as reimbursed through Medicare is in the order of $250 to 300 per visit. Many of these costs or lost revenues may be mitigated by effective emergency preparedness planning. For a non-ESRD individual who cannot receive care from his or her office-based physician but must instead go to an emergency room, not only are the individual's costs increased, but reimbursement through Medicare, Medicaid or private insurance is also increased. AHRQ's Medical Expenditure Panel Survey from 2008 notes that the average expense for an office based visit was $199 versus $922 for an emergency room visit (Machlin, S., and Chowdhury, S. "Expenses and Characteristics of Physician Visits in Different Ambulatory Care Settings, 2008." Statistical Brief #318. March 2011. Agency for Healthcare Research and Quality, Rockville, MD. *http://www.meps.ahrq.gov/mepsweb/data_files/publications/st318/stat318.pdf*).

With the annualized costs of the rule's emergency preparedness requirements estimated to be approximately $100 million depending on the discount rate used (see the accounting statement table that follows) and the rule generating additional, unquantified costs associated with the life-saving activities that become implementable as a result of the preparedness requirements, this final rule will have to result in at least $100 million in average yearly benefits, principally derived from reductions in morbidity and mortality, for the benefits to equal or exceed costs. ASPR and CMS, using Medicare claims data, conducted an analysis of the impact of Hurricane Sandy on dialysis-dependent ESRD patients. The study found a significant increase in emergency department visits, hospitalizations, and 30-day mortality for ESRD patients living in the areas most affected by the storm (Kelman, et al.). Approximately 23 percent of the study patients who had an emergency visit also received dialysis in the ED during their visits (Kelman, et al.). (Kelman, Jeffrey, et al. "Dialysis care and death following Hurricane Sandy." American Journal of Kidney Diseases 65.1 (2015): 109–115.) Adoption of the following requirements in this final rule will better enable individual facilities to—

- Anticipate threats;
- Rapidly activate plans, processes and protocols;
- Quickly communicate with their patients, other facilities and state or local officials to ensure continuity of care for these life maintaining services; and
- Reduce healthcare system stress by remaining open or re-opening quickly following closure. This will decrease the rate of interrupted dialysis, thereby reducing preventable ED visits, hospitalizations, and mortality during and following disasters.

W. Alternatives Considered

1. No Regulatory Action

As previously discussed, the status quo is not a desirable alternative because the current regulatory requirements for Medicare and Medicaid providers and suppliers addressing emergency and disaster preparedness are insufficient to protect beneficiaries and other patients during a disaster.

2. Defer to Federal, State, and Local Laws

Another alternative we considered was to propose a regulation that would require Medicare providers and suppliers to comply with local, state and federal laws regarding emergency and disaster planning. Various federal, state and local entities (FEMA, the National Response Plan (NRP), CDC, the Assistant Secretary for Preparedness and Response (ASPR), et al) have disaster management plans that provide an integrated process that involves all local and regional emergency responders. We also considered allowing healthcare providers to voluntarily implement a comprehensive emergency preparedness program utilizing grant funding from the Office of the Assistant Secretary for Preparedness and Response, (ASPR). Based on a 2010 survey of the American College of Healthcare Executives (ACHE), less than 1 percent of hospital CEOs identified "disaster preparedness" as a top priority. Also, a 2012 survey of 1,202 community hospital CEOs (found at: *http://www.ache.org/Pubs/Releases/2013/Top-Issues-Confronting-Hospitals-2012.cfm*) of ASPR's Hospital Preparedness Program (HPP) showed that disaster preparedness was not identified as a top issue. We believe that absent conditions of participation, certification, and coverage, providers and suppliers will not consistently adhere to the various local, state and federal emergency preparedness requirements. Moreover, many such instructions are unclear as to what is mandatory or only strongly recommended, and written in ways that leave compliance difficult or impossible to determine consistently across providers. Such inconsistent application of local, state, and federal requirements could compound the problems faced by governments, healthcare organizations, and citizens during a disaster. In addition, our regulations will enable us to survey and enforce the emergency preparedness requirements using standard processes and criteria.

3. Conclusion

We currently have regulations for Medicare and Medicaid providers and suppliers to protect the health and safety of Medicare beneficiaries and others. We revise these regulations on an as-needed basis to address changes in clinical practice, patient needs, and public health issues. The responses to the various past disasters demonstrated that our current regulations are in need of improvement in order to protect patients, residents, and clients during an emergency and that emergency preparedness for healthcare providers and suppliers is an urgent public health issue. Therefore, we are finalizing emergency preparedness requirements that are consistent and enforceable for all Medicare and Medicaid providers and suppliers. This final rule addresses the three key elements needed to ensure that healthcare is available during emergencies: Safeguarding human resources, ensuring business continuity, and protecting physical resources. Current regulations for Medicare and Medicaid providers and suppliers do not adequately address these key elements.

X. Costs to Federal Government

Surveyors will be trained and interpretive guidelines will be developed. If these requirements are finalized, we will update the interpretive guidance, update the survey process, and make IT systems changes. In order to implement these new standards, we anticipate initial federal start-up costs to be $700,000. Once implemented, surveys will begin in FY17 and we anticipate initial costs for these surveys to carry into FY18 due to the survey cycle. Therefore, we anticipate approximately $4,411,286 for FY18 with a decrease in subsequent years to an estimated $3,749,593 annually in federal costs.

Y. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circular/a004/a-4.pdf*), we have prepared an accounting statement. As previously explained, achieving the full scope of potential savings will depend on the number of lives affected or saved as a result of this regulation.

TABLE 132—ACCOUNTING STATEMENT

Category	Estimates	Units		
		Year dollar	Discount rate	Period covered
Benefits				
Qualitative	Help ensure the safety of individuals by requiring providers and suppliers to adequately plan for and respond to both natural and man-made disasters.			
Costs *				
Annualized Monetized ($million/year)	104	2015	7%	2016–2020
	99	2015	3%	2016–2020
Qualitative	Costs of performing life-saving and morbidity-reducing activities during emergency events.			

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

Comment: A commenter stated that the figures used for economic impact, not including the ICR burden are underestimated by 45 percent. Several other commenters stated that they believe that our projections of burden and cost for compliance with the proposed rule are underestimated. They stated that many hospitals, especially smaller hospitals, have expressed concern about the financial implications for compliance with certain provisions, especially the additional generator testing. In addition, they stated that we underestimated the amount of time and work it will take many providers and suppliers to come into compliance with the proposed requirements. For example, tasks such as updating policies and procedures involve more than assembling key hospital staff to attend a limited number of meetings, draft revisions and obtain approval. Updating policies and procedures also involves researching alternatives, assessing any costs involved (such as technology that may be needed), reviewing potential changes with employees who may be affected, implementing the changes, training staff and testing outcomes.

Response: We appreciate all of the public comments we received regarding the cost and burden estimates for this rule. We carefully reviewed the public comments and have discussed many of the comments that will reduce burden under previous sections of this rule. We have increased the overhead cost to 100 percent of salary. In addition, based on our experience with the Medicare and Medicaid providers, most providers have some type of an emergency plan and agree that it is very important to appropriately plan for a potential emergency or disaster. We believe that these providers currently inform or train their staff on some type of an emergency plan with various degrees of effectiveness. We realize that these requirements will require providers and suppliers to consistently conduct additional assessment, and development of policies and procedures and have added additional cost for the projected personnel time associated with this rule.

As previously discussed, we will remove the burden and cost for hospitals, CAHs and LTC facilities to conduct an additional testing of their generators. We have also provided flexibility under the training and testing requirements and we have increased the salary cost for the staff that will participate in complying with this rule.

VI. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposal. The notice of proposed rule includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

In various sections of the December 2013 proposed rule (78 FR 79101), we referenced the latest version of the Life Safety Code (NFPA® 101), the Health Care Facilities Code (NFPA® 99) and the Standard for Standby Power Generators (NFPA® 110). In the May 4, 2016 **Federal Register** (81 FR 26872) we published a final rule, "Medicare and Medicaid Programs: Fire Safety Requirements for Certain Health Care Facilities", which incorporated by reference the 2012 editions of NFPA® 101, "Life Safety Code" and NFPA® 99, "Health Care Facilities Code" into our regulations. In a similar manner in this final rule, we are incorporating by reference the 2012 editions of NFPA® 101, "Life Safety Code" and NFPA® 99, "Health Care Facilities Code" as well as the 2010 edition of NFPA® 110, Standard for Emergency and Standby Power Systems. Because the December 2013 proposed rule referred to and discussed incorporation of earlier versions of these NFPA documents, we believe that engaging in a new round of notice-and-comment rulemaking to propose an update to these codes, which have already been incorporated into our general fire safety regulations, would be both unnecessary and contrary to the public interest. Therefore, we find good cause to waive the notice of proposed rulemaking related to these changes.

List of Subjects

42 CFR Part 403

Grant programs-health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 441

Aged, Family planning, Grant programs-health, Infants and children, Medicaid, Penalties, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs-health, Hospitals, Medicaid, Incorporation by reference, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs-health, Health facilities, Health professions, Health records, Incorporation by Reference, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs-health, Health facilities, Incorporation by Reference, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 486

Grant programs-health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 491

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 494

Health facilities, Incorporation by reference, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 continues to read as follows:

Authority: 42 U.S.C. 1395b-3 and Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 403.742 [Amended]

■ 2. Amend § 403.742 by—

■ a. Removing paragraphs (a)(1), (4), and (5).

■ b. Redesignating paragraphs (a)(2) and (3) as paragraphs (a)(1) and (2), respectively.

■ c. Redesignating paragraphs (a)(6) through (8) as paragraphs (a)(3) through (5), respectively.

■ 3. Add § 403.748 to read as follows:

§ 403.748 Condition of participation: Emergency preparedness.

The Religious Nonmedical Health Care Institution (RNHCI) must comply with all applicable Federal, State, and local emergency preparedness requirements. The RNHCI must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The RNHCI must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, persons at-risk; the type of services the RNHCI has the ability to provide in an emergency; and, continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the RNHCI's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The RNHCI must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, and supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered patients in the RNHCI's care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the RNCHI must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the RNHCI, which includes the following:

(i) Consideration of care needs of evacuees.

(ii) Staff responsibilities.

(iii) Transportation.

(iv) Identification of evacuation location(s).

(v) Primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(5) A system of care documentation that does the following:

(i) Preserves patient information.

(ii) Protects confidentiality of patient information.

(iii) Secures and maintains the availability of records.

(6) The use of volunteers in an emergency and other emergency staffing strategies to address surge needs during an emergency.

(7) The development of arrangements with other RNHCIs and other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of nonmedical services to RNHCI patients.

(8) The role of the RNHCI under a waiver declared by the Secretary, in accordance with section 1135 of Act, in the provision of care at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The RNHCI must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Next of kin, guardian or custodian.

(iv) Other RNHCIs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) RNHCI's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and care documentation for patients under the RNHCI's care, as necessary, with care providers to maintain the continuity of care, based on the written election statement made by the patient or his or her legal representative.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the RNHCI's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The RNHCI must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The RNHCI must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of all emergency preparedness training.

(iv) Demonstrate staff knowledge of emergency procedures.

(2) *Testing.* The RNHCI must conduct exercises to test the emergency plan. The RNHCI must do the following:

(i) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(ii) Analyze the RNHCI's response to and maintain documentation of all tabletop exercises, and emergency events, and revise the RNHCI's emergency plan, as needed.

PART 416—AMBULATORY SURGICAL SERVICES

■ 4. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 416.41 [Amended]

■ 5. Amend § 416.41 by removing paragraph (c).

■ 6. Add § 416.54 to subpart C to read as follows:

§ 416.54 Condition for coverage—Emergency preparedness.

The Ambulatory Surgical Center (ASC) must comply with all applicable Federal, State, and local emergency preparedness requirements. The ASC must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The ASC must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, the type of services the ASC has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency

preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the ASC's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The ASC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of on-duty staff and sheltered patients in the ASC's care during an emergency. If on-duty staff or sheltered patients are relocated during the emergency, the ASC must document the specific name and location of the receiving facility or other location.

(2) Safe evacuation from the ASC, which includes the following:

(i) Consideration of care and treatment needs of evacuees.

(ii) Staff responsibilities.

(iii) Transportation.

(iv) Identification of evacuation location(s).

(v) Primary and alternate means of communication with external sources of assistance.

(3) A means to shelter in place for patients, staff, and volunteers who remain in the ASC.

(4) A system of medical documentation that does the following:

(i) Preserves patient information.

(ii) Protects confidentiality of patient information.

(iii) Secures and maintains the availability of records.

(5) The use of volunteers in an emergency and other staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(6) The role of the ASC under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The ASC must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) ASC's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the ASC's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the ASC's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The ASC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The ASC must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of all emergency preparedness training.

(iv) Demonstrate staff knowledge of emergency procedures.

(2) *Testing.* The ASC must conduct exercises to test the emergency plan at least annually. The ASC must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, individual, facility-based. If the ASC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ASC is exempt from engaging in an community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the ASC's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the ASC's emergency plan, as needed.

(e) *Integrated healthcare systems.* If an ASC is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the ASC may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must—

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements

set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

PART 418—HOSPICE CARE

■ 7. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 418.110 [Amended]

■ 8. Amend § 418.110 by removing paragraph (c)(1)(ii) and the paragraph designation (i) from paragraph (c)(1)(i).

■ 9. Add § 418.113 to read as follows:

§ 418.113 Condition of participation: Emergency preparedness.

The hospice must comply with all applicable Federal, State, and local emergency preparedness requirements. The hospice must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The hospice must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment, including the management of the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care.

(3) Address patient population, including, but not limited to, the type of services the hospice has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, or Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the hospice's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The hospice must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) Procedures to follow up with on-duty staff and patients to determine services that are needed, in the event that there is an interruption in services during or due to an emergency. The hospice must inform State and local officials of any on-duty staff or patients that they are unable to contact.

(2) Procedures to inform State and local officials about hospice patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment.

(3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

(4) The use of hospice employees in an emergency and other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(5) The development of arrangements with other hospices and other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to hospice patients.

(6) The following are additional requirements for hospice-operated inpatient care facilities only. The policies and procedures must address the following:

(i) A means to shelter in place for patients, hospice employees who remain in the hospice.

(ii) Safe evacuation from the hospice, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s) and primary and alternate means of communication with external sources of assistance.

(iii) The provision of subsistence needs for hospice employees and patients, whether they evacuate or shelter in place, include, but are not limited to the following:

(A) Food, water, medical, and pharmaceutical supplies.

(B) Alternate sources of energy to maintain the following:

(*1*) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.

(*2*) Emergency lighting.

(*3*) Fire detection, extinguishing, and alarm systems.

(C) Sewage and waste disposal.

(iv) The role of the hospice under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(v) A system to track the location of hospice employees' on-duty and sheltered patients in the hospice's care during an emergency. If the on-duty employees or sheltered patients are relocated during the emergency, the hospice must document the specific name and location of the receiving facility or other location.

(c) *Communication plan.* The hospice must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Hospice employees.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other hospices.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) Hospice's employees.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the hospice's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the hospice's inpatient occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The hospice must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The hospice must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing hospice employees, and individuals providing services under arrangement, consistent with their expected roles.

(ii) Demonstrate staff knowledge of emergency procedures.

(iii) Provide emergency preparedness training at least annually.

(iv) Periodically review and rehearse its emergency preparedness plan with hospice employees (including nonemployee staff), with special emphasis placed on carrying out the procedures necessary to protect patients and others.

(v) Maintain documentation of all emergency preparedness training.

(2) *Testing.* The hospice must conduct exercises to test the emergency plan at least annually. The hospice must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the hospice experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the hospice's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the hospice's emergency plan, as needed.

(e) *Integrated healthcare systems.* If a hospice is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the hospice may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

■ 10. The authority citation for part 441 continues to read as follows:

Authority: Secs. 1102, 1902, and 1928 of the Social Security Act (42 U.S.C. 1302).

■ 11. Add § 441.184 to subpart D to read as follows:

§ 441.184 Emergency preparedness.

The Psychiatric Residential Treatment Facility (PRTF) must comply with all applicable Federal, State, and local emergency preparedness requirements. The PRTF must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The PRTF must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address resident population, including, but not limited to, persons at-risk; the type of services the PRTF has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the PRTF's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The PRTF must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and residents, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, medical, and pharmaceutical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect resident health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered residents in the PRTF's care during and after an emergency. If on-duty staff and sheltered residents are relocated during the emergency, the PRTF must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the PRTF, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s);

and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for residents, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves resident information, protects confidentiality of resident information, and secures and maintains the availability of records.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other PRTFs and other providers to receive residents in the event of limitations or cessation of operations to maintain the continuity of services to PRTF residents.

(8) The role of the PRTF under a waiver declared by the Secretary, in accordance with section 1135 of Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The PRTF must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Residents' physicians.

(iv) Other PRTFs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the PRTF's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for residents under the PRTF's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release resident information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of residents under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the PRTF's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The PRTF must develop and maintain an emergency preparedness training program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The PRTF must do all of the following:

(i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) After initial training, provide emergency preparedness training at least annually.

(iii) Demonstrate staff knowledge of emergency procedures.

(iv) Maintain documentation of all emergency preparedness training.

(2) *Testing.* The PRTF must conduct exercises to test the emergency plan. The PRTF must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the PRTF experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PRTF is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the PRTF's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the PRTF's emergency plan, as needed.

(e) *Integrated healthcare systems.* If a PRTF is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the PRTF may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 12. The authority citation for part 460 continues to read as follows:

Authority: Secs: 1102, 1871, 1894(f), and 1934(f) of the Social Security Act (42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f)).

§ 460.72 [Amended]

■ 13. Amend § 460.72 by removing and reserving paragraph (c).

■ 14. Add § 460.84 to subpart E to read as follows:

§ 460.84 Emergency preparedness.

The Program for the All-Inclusive Care for the Elderly (PACE) organization must comply with all applicable Federal, State, and local emergency preparedness requirements. The PACE organization must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The PACE organization must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address participant population, including, but not limited to, the type of services the PACE organization has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the PACE's efforts to contact such officials and, when applicable, of its participation in organization's collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The PACE organization must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must address management of medical and nonmedical emergencies, including, but not limited to: Fire; equipment, power, or water failure; care-related emergencies; and natural disasters likely to threaten the health or safety of the participants, staff, or the public. Policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and participants, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, and medical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect participant health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered participants under the PACE center(s) care during and after an emergency. If on-duty staff and sheltered participants are relocated during the emergency, the PACE must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the PACE center, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) The procedures to inform State and local emergency preparedness officials about PACE participants in need of evacuation from their residences at any time due to an emergency situation based on the participant's medical and psychiatric conditions and home environment.

(5) A means to shelter in place for participants, staff, and volunteers who remain in the facility.

(6) A system of medical documentation that preserves participant information, protects confidentiality of participant information, and secures and maintains the availability of records.

(7) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(8) The development of arrangements with other PACE organizations, PACE centers, or other providers to receive participants in the event of limitations or cessation of operations to maintain the continuity of services to PACE participants.

(9) The role of the PACE organization under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(10)(i) Emergency equipment, including easily portable oxygen, airways, suction, and emergency drugs.

(ii) Staff who know how to use the equipment must be on the premises of every center at all times and be immediately available.

(iii) A documented plan to obtain emergency medical assistance from outside sources when needed.

(c) *Communication plan.* The PACE organization must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for staff; entities providing services under arrangement; participants' physicians; other PACE organizations; and volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) PACE organization's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for participants under the organization's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release participant information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of participants under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the PACE organization's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The PACE organization must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The PACE organization must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, contractors, participants, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Demonstrate staff knowledge of emergency procedures, including informing participants of what to do, where to go, and whom to contact in case of an emergency.

(iv) Maintain documentation of all training.

(2) *Testing.* The PACE organization must conduct exercises to test the emergency plan at least annually. The PACE organization must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the PACE experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PACE is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the PACE's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the PACE's emergency plan, as needed.

(e) *Integrated healthcare systems.* If a PACE is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the PACE may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must—

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, participant populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 15. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

■ 16. Add § 482.15 to subpart B to read as follows:

§ 482.15 Condition of participation: Emergency preparedness.

The hospital must comply with all applicable Federal, State, and local emergency preparedness requirements. The hospital must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The hospital must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, persons at-risk; the type of services the hospital has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the hospital's efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The hospital must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, medical, and pharmaceutical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered patients in the hospital's care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the hospital must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the hospital, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

(6) The use of volunteers in an emergency and other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other hospitals and other providers to receive patients in the event of limitations or cessation of operations to

maintain the continuity of services to hospital patients.

(8) The role of the hospital under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The hospital must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other hospitals and CAHs

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) Hospital's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the hospital's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the hospital's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The hospital must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The hospital must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected role.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures.

(2) *Testing.* The hospital must conduct exercises to test the emergency plan at least annually. The hospital must do all of the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the hospital experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the hospital's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan, as needed.

(e) *Emergency and standby power systems.* The hospital must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section and in the policies and procedures plan set forth in paragraphs (b)(1)(i) and (ii) of this section.

(1) *Emergency generator location.* The generator must be located in accordance with the location requirements found in the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5, and TIA 12–6), Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.

(2) *Emergency generator inspection and testing.* The hospital must implement the emergency power system inspection, testing, and maintenance requirements found in the Health Care Facilities Code, NFPA 110, and Life Safety Code.

(3) *Emergency generator fuel.* Hospitals that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

(f) *Integrated healthcare systems.* If a hospital is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the hospital may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must—

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

(g) *Transplant hospitals.* If a hospital has one or more transplant centers (as defined in § 482.70)—

(1) A representative from each transplant center must be included in the development and maintenance of the hospital's emergency preparedness program; and

(2) The hospital must develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the hospital, each

transplant center, and the OPO for the DSA where the hospital is situated, unless the hospital has been granted a waiver to work with another OPO, during an emergency.

(h) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain the material from the sources listed below. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the **Federal Register** to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, *www.nfpa.org,* 1.617.770.3000.

(i) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11, 2011.

(ii) Technical interim amendment (TIA) 12–2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12–3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12–4 to NFPA 99, issued March 7, 2013.

(v) TIA 12–5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12–6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.

(viii) TIA 12–1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12–2 to NFPA 101, issued October 30, 2012.

(x) TIA 12–3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12–4 to NFPA 101, issued October 22, 2013.

(xiii) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

(2) [Reserved]

■ 17. Revise § 482.68 to read as follows:

§ 482.68 Special requirement for transplant centers.

A transplant center located within a hospital that has a Medicare provider agreement must meet the conditions of participation specified in §§ 482.72 through 482.104 in order to be granted approval from CMS to provide transplant services.

(a) Unless specified otherwise, the conditions of participation at §§ 482.72 through 482.104 apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers.

(b) In addition to meeting the conditions of participation specified in §§ 482.72 through 482.104, a transplant center must also meet the conditions of participation in §§ 482.1 through 482.57, except for § 482.15.

■ 18. Add § 482.78 to read as follows:

§ 482.78 Condition of participation: Emergency preparedness for transplant centers.

A transplant center must be included in the emergency preparedness planning and the emergency preparedness program as set forth in § 482.15 for the hospital in which it is located. However, a transplant center is not individually responsible for the emergency preparedness requirements set forth in § 482.15.

(a) *Standard: Policies and procedures.* A transplant center must have policies and procedures that address emergency preparedness. These policies and procedures must be included in the hospital's emergency preparedness program.

(b) *Standard: Protocols with hospital and OPO.* A transplant center must develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the transplant center, the hospital in which the transplant center is operated, and the OPO designated by the Secretary, unless the hospital has an approved waiver to work with another OPO, during an emergency.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 19. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102, 1128I, 1819, 1871 and 1919 of the Social Security Act (42 U.S.C. 1302, 1320a–7, 1395i, 1395hh and 1396r).

■ 20. Add § 483.73 to read as follows:

§ 483.73 Emergency preparedness.

The LTC facility must comply with all applicable Federal, State and local emergency preparedness requirements. The LTC facility must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The LTC facility must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, including missing residents.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address resident population, including, but not limited to, persons at-risk; the type of services the LTC facility has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, or Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the LTC facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The LTC facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and residents, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, medical, and pharmaceutical supplies.

(ii) Alternate sources of energy to maintain—

(A) Temperatures to protect resident health and safety and for the safe and sanitary storage of provisions;

(B) Emergency lighting;

(C) Fire detection, extinguishing, and alarm systems; and

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered residents in the LTC facility's care during and after an emergency. If on-duty staff and sheltered residents are relocated during the emergency, the LTC facility must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the LTC facility, which includes consideration of

care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for residents, staff, and volunteers who remain in the LTC facility.

(5) A system of medical documentation that preserves resident information, protects confidentiality of resident information, and secures and maintains the availability of records.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other LTC facilities and other providers to receive residents in the event of limitations or cessation of operations to maintain the continuity of services to LTC residents.

(8) The role of the LTC facility under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The LTC facility must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Residents' physicians.

(iv) Other LTC facilities.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, or local emergency preparedness staff.

(ii) The State Licensing and Certification Agency.

(iii) The Office of the State Long-Term Care Ombudsman.

(iv) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) LTC facility's staff.

(ii) Federal, State, tribal, regional, or local emergency management agencies.

(4) A method for sharing information and medical documentation for residents under the LTC facility's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release resident information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of residents under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the LTC facility's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(8) A method for sharing information from the emergency plan that the facility has determined is appropriate with residents and their families or representatives.

(d) *Training and testing.* The LTC facility must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The LTC facility must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures.

(2) *Testing.* The LTC facility must conduct exercises to test the emergency plan at least annually, including unannounced staff drills using the emergency procedures. The LTC facility must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the LTC facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the LTC facility is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the LTC facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the LTC facility's emergency plan, as needed.

(e) *Emergency and standby power systems.* The LTC facility must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section.

(1) *Emergency generator location.* The generator must be located in accordance with the location requirements found in the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5, and TIA 12–6), Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.

(2) *Emergency generator inspection and testing.* The LTC facility must implement the emergency power system inspection, testing, and maintenance requirements found in the Health Care Facilities Code, NFPA 110, and Life Safety Code.

(3) *Emergency generator fuel.* LTC facilities that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

(f) *Integrated healthcare systems.* If a LTC facility is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the LTC facility may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include—

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

(g) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain the material from the sources listed below. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the **Federal Register** to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, *www.nfpa.org*, 1.617.770.3000.

(i) NFPA 99, Health Care Facilities Code 2012 edition, issued August 11, 2011.

(ii) Technical interim amendment (TIA) 12–2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12–3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12–4 to NFPA 99, issued March 7, 2013.

(v) TIA 12–5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12–6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.

(viii) TIA 12–1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12–2 to NFPA 101, issued October 30, 2012.

(x) TIA 12–3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12–4 to NFPA 101, issued October 22, 2013.

(xiii) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

(2) [Reserved]

§ 483.75 [Amended]

■ 21. Amend § 483.75 by removing and reserving paragraph (m).

§ 483.470 [Amended]

■ 22. Amend § 483.470 by removing and reserving paragraph (h).

■ 23. Add § 483.475 to read as follows:

§ 483.475 Condition of participation: Emergency preparedness.

The Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID) must comply with all applicable Federal, State, and local emergency preparedness requirements. The ICF/IID must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The ICF/IID must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, including missing clients.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address the special needs of its client population, including, but not limited to, persons at-risk; the type of services the ICF/IID has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the ICF/IID efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The ICF/IID must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and clients, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, medical, and pharmaceutical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect client health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered clients in the ICF/IID's care during and after an emergency. If on-duty staff and sheltered clients are relocated during the emergency, the ICF/IID must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the ICF/IID, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for clients, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves client information, protects confidentiality of client information, and secures and maintains the availability of records.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other ICF/IIDs or other providers to receive clients in the event of limitations or cessation of operations to maintain the continuity of services to ICF/IID clients.

(8) The role of the ICF/IID under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at

an alternate care site identified by emergency management officials.

(c) *Communication plan.* The ICF/IID must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Clients' physicians.

(iv) Other ICF/IIDs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(iii) The State Licensing and Certification Agency.

(iv) The State Protection and Advocacy Agency.

(3) Primary and alternate means for communicating with the ICF/IID's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for clients under the ICF/IID's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release client information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of clients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the ICF/IID's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(8) A method for sharing information from the emergency plan that the facility has determined is appropriate with clients and their families or representatives.

(d) *Training and testing.* The ICF/IID must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually. The ICF/IID must meet the requirements for evacuation drills and training at § 483.470(h).

(1) *Training program.* The ICF/IID must do all the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures.

(2) *Testing.* The ICF/IID must conduct exercises to test the emergency plan at least annually. The ICF/IID must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the ICF/IID experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ICF/IID is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the ICF/IID's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the ICF/IID's emergency plan, as needed.

(e) *Integrated healthcare systems.* If an ICF/IID is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the ICF/IID may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

PART 484—HOME HEALTH SERVICES

■ 24. The authority citation for part 484 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

■ 25. Add § 484.22 to subpart B to read as follows:

§ 484.22 Condition of participation: Emergency preparedness.

The Home Health Agency (HHA) must comply with all applicable Federal, State, and local emergency preparedness requirements. The HHA must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The HHA must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, the type of services the HHA has the ability to provide in an emergency; and continuity of operations, including

delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the HHA's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The HHA must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The plans for the HHA's patients during a natural or man-made disaster. Individual plans for each patient must be included as part of the comprehensive patient assessment, which must be conducted according to the provisions at § 484.55.

(2) The procedures to inform State and local emergency preparedness officials about HHA patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment.

(3) The procedures to follow up with on-duty staff and patients to determine services that are needed, in the event that there is an interruption in services during or due to an emergency. The HHA must inform State and local officials of any on-duty staff or patients that they are unable to contact.

(4) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

(5) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(c) *Communication plan.* The HHA must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, or local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the HHA's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the HHA's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(6) A means of providing information about the HHA's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The HHA must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The HHA must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(ii) Demonstrate staff knowledge of emergency procedures.

(2) *Testing.* The HHA must conduct exercises to test the emergency plan at least annually. The HHA must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the HHA experiences an actual natural or man-made emergency that requires activation of the emergency plan, the HHA is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the HHA's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the HHA's emergency plan, as needed.

(e) *Integrated healthcare systems.* If a HHA is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the HHA may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet

the requirements of paragraphs (c) and (d) of this section, respectively.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 26. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

§ 485.64 [Removed and Reserved]

■ 27. Remove and reserve § 485.64.

■ 28. Add § 485.68 to read as follows:

§ 485.68 Condition of participation: Emergency preparedness.

The Comprehensive Outpatient Rehabilitation Facility (CORF) must comply with all applicable Federal, State, and local emergency preparedness requirements. The CORF must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The CORF must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, the type of services the CORF has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the CORF's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts;

(5) Be developed and maintained with assistance from fire, safety, and other appropriate experts.

(b) *Policies and procedures.* The CORF must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) Safe evacuation from the CORF, which includes staff responsibilities, and needs of the patients.

(2) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

(4) The use of volunteers in an emergency and other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(c) *Communication plan.* The CORF must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other CORFs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the CORF's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the CORF's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means of providing information about the CORF's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) *Training and testing.* The CORF must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The CORF must do all of the following:

(i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures. All new personnel must be oriented and assigned specific responsibilities regarding the CORF's emergency plan within 2 weeks of their first workday. The training program must include instruction in the location and use of alarm systems and signals and firefighting equipment.

(2) *Testing.* The CORF must conduct exercises to test the emergency plan at least annually. The CORF must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the CORF experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CORF is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the CORF's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CORF's emergency plan, as needed.

(e) *Integrated healthcare systems.* If a CORF is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the CORF may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community–based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

§ 485.623 [Amended]

■ 29. Amend § 485.623 by removing paragraph (c) and redesignating paragraphs (d) through (f) as paragraphs (c) through (e).

■ 30. Adding § 485.625 to subpart F to read as follows:

§ 485.625 Condition of participation: Emergency preparedness.

The CAH must comply with all applicable Federal, State, and local emergency preparedness requirements. The CAH must develop and maintain a comprehensive emergency preparedness program, utilizing an all-hazards approach. The emergency preparedness plan must include, but not be limited to, the following elements:

(a) *Emergency plan.* The CAH must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, persons at-risk; the type of services the CAH has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the CAH's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The CAH must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to—

(i) Food, water, medical, and pharmaceutical supplies;

(ii) Alternate sources of energy to maintain:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions;

(B) Emergency lighting;

(C) Fire detection, extinguishing, and alarm systems; and

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered patients in the CAH's care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the CAH must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the CAH, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other CAHs or other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to CAH patients.

(8) The role of the CAH under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The CAH must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other CAHs and hospitals.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) CAH's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the CAH's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the CAH's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) *Training and testing.* The CAH must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The CAH must do all of the following:

(i) Initial training in emergency preparedness policies and procedures, including prompt reporting and extinguishing of fires, protection, and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with firefighting and disaster authorities, to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures.

(2) *Testing.* The CAH must conduct exercises to test the emergency plan at least annually. The CAH must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based exercise. If the CAH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CAH is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the CAH's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CAH's emergency plan, as needed.

(e) *Emergency and standby power systems.* The CAH must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section.

(1) *Emergency generator location.* The generator must be located in accordance with the location requirements found in the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5, and TIA 12–6), Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.

(2) *Emergency generator inspection and testing.* The CAH must implement emergency power system inspection and testing requirements found in the Health Care Facilities Code, NFPA 110, and the Life Safety Code.

(3) *Emergency generator fuel.* CAHs that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

(f) *Integrated healthcare systems.* If a CAH is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the CAH may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include—

(i) A documented community–based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

(g) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain the material from the sources listed below. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the **Federal Register** to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, *www.nfpa.org,* 1.617.770.3000.

(i) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11, 2011.

(ii) Technical interim amendment (TIA) 12–2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12–3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12–4 to NFPA 99, issued March 7, 2013.

(v) TIA 12–5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12–6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.

(viii) TIA 12–1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12–2 to NFPA 101, issued October 30, 2012.

(x) TIA 12–3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12–4 to NFPA 101, issued October 22, 2013.

(xiii) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

(2) [Reserved]

■ 31. Revise § 485.727 to read as follows:

§ 485.727 Condition of participation: Emergency preparedness.

The Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services ("Organizations") must comply with all applicable Federal, State, and local emergency preparedness requirements. The Organizations must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The Organizations must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, the type of services the Organizations have the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Address the location and use of alarm systems and signals; and methods of containing fire.

(5) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(6) Be developed and maintained with assistance from fire, safety, and other appropriate experts.

(b) *Policies and procedures.* The Organizations must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) Safe evacuation from the Organizations, which includes staff responsibilities, and needs of the patients.

(2) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

(4) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(c) *Communication plan.* The Organizations must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other Organizations.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, state, tribal, regional and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) Organizations' staff.

(ii) Federal, state, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the Organizations' care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means of providing information about the Organizations' needs, and their ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) *Training and testing.* The Organizations must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The Organizations must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures.

(2) *Testing.* The Organizations must conduct exercises to test the emergency plan at least annually. The Organizations must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the Organizations experience an actual natural or man-made emergency that requires activation of the emergency plan, the organization is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the Organization's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise their emergency plan, as needed.

(e) *Integrated healthcare systems.* If the Organizations are part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the Organizations may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

■ 32. Add § 485.920 to read as follows:

§ 485.920 Condition of participation: Emergency preparedness.

The Community Mental Health Center (CMHC) must comply with all applicable Federal, State, and local emergency preparedness requirements. The CMHC must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The CMHC must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address client population, including, but not limited to, the type of services the CMHC has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the CMHC's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The CMHC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of on-duty staff and sheltered clients in the CMHC's care during and after an emergency. If on-duty staff and sheltered clients are relocated during the emergency, the CMHC must document the specific name and location of the receiving facility or other location.

(2) Safe evacuation from the CMHC, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(3) A means to shelter in place for clients, staff, and volunteers who remain in the facility.

(4) A system of medical documentation that preserves client information, protects confidentiality of client information, and secures and maintains the availability of records.

(5) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of state or Federally designated health care professionals to address surge needs during an emergency.

(6) The development of arrangements with other CMHCs or other providers to receive clients in the event of limitations or cessation of operations to maintain the continuity of services to CMHC clients.

(7) The role of the CMHC under a waiver declared by the Secretary of Health and Human Services, in accordance with section 1135 of the Social Security Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The CMHC must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Clients' physicians.

(iv) Other CMHCs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) CMHC's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for clients under the CMHC's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release client information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of clients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the CMHC's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) *Training and testing.* The CMHC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training.* The CMHC must provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. The CMHC must demonstrate staff knowledge of emergency procedures. Thereafter, the CMHC must provide emergency preparedness training at least annually.

(2) *Testing.* The CMHC must conduct exercises to test the emergency plan at least annually. The CMHC must:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the CMHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CMHC is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the CMHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CMHC's emergency plan, as needed.

(e) *Integrated healthcare systems.* If a CMHC is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the CMHC may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

■ 33. The authority citation for part 486 continues to read as follows:

Authority: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b–8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C 273).

■ 34. Add § 486.360 to read as follows:

§ 486.360 Condition for Coverage: Emergency preparedness.

The Organ Procurement Organization (OPO) must comply with all applicable Federal, State, and local emergency preparedness requirements. The OPO must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The OPO must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address the type of hospitals with which the OPO has agreements; the type of services the OPO has the capacity to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the OPO's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The OPO must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and, the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of on-duty staff during and after an emergency. If on-duty staff is relocated during the emergency, the OPO must document the specific name and location of the receiving facility or other location.

(2) A system of medical documentation that preserves potential and actual donor information, protects confidentiality of potential and actual donor information, and secures and maintains the availability of records.

(c) *Communication plan.* The OPO must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Volunteers.

(iv) Other OPOs.

(v) Transplant and donor hospitals in the OPO's Donation Service Area (DSA).

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) OPO's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(d) *Training and testing.* The OPO must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training.* The OPO must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures.

(2) *Testing.* The OPO must conduct exercises to test the emergency plan. The OPO must do the following:

(i) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(ii) Analyze the OPO's response to and maintain documentation of all tabletop exercises, and emergency events, and revise the OPO's emergency plan, as needed.

(e) *Continuity of OPO operations during an emergency.* Each OPO must have a plan to continue operations during an emergency.

(1) The OPO must develop and maintain in the protocols with transplant programs required under § 486.344(d), mutually agreed upon protocols that address the duties and responsibilities of the transplant program, the hospital in which the transplant program is operated, and the OPO during an emergency.

(2) The OPO must have the capability to continue its operation from an alternate location during an emergency. The OPO could either have:

(i) An agreement with one or more other OPOs to provide essential organ procurement services to all or a portion of its DSA in the event the OPO cannot provide those services during an emergency;

(ii) If the OPO has more than one location, an alternate location from which the OPO could conduct its operation; or

(iii) A plan to relocate to another location as part of its emergency plan as required by paragraph (a) of this section.

(f) *Integrated healthcare systems.* If an OPO is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the OPO may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

■ 35. The authority citation for part 491 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

§ 491.6 [Amended]

■ 36. Amend § 491.6 by removing paragraph (c).

■ 37. Add § 491.12 to read as follows:

§ 491.12 Emergency preparedness.

The Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) must comply with all applicable Federal, State, and local emergency preparedness requirements. The RHC/FQHC must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The RHC/FQHC must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, the type of services the RHC/FQHC has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the RHC/FQHC's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The RHC/FQHC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) Safe evacuation from the RHC/FQHC, which includes appropriate placement of exit signs; staff responsibilities and needs of the patients.

(2) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(3) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

(4) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(c) *Communication plan.* The RHC/FQHC must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other RHCs/FQHCs.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) RHC/FQHC's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(5) A means of providing information about the RHC/FQHC's needs, and its

ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) *Training and testing.* The RHC/FQHC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The RHC/FQHC must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles,

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures.

(2) *Testing.* The RHC/FQHC must conduct exercises to test the emergency plan at least annually. The RHC/FQHC must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the RHC/FQHC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the RHC/FQHC is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the RHC/FQHC's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the RHC/FQHC's emergency plan, as needed.

(e) *Integrated healthcare systems.* If a RHC/FQHC is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the RHC/FQHC may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following:

(i) A documented community–based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan, and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

■ 38. The authority citation for part 494 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 494.60 [Amended]

■ 39. Amend § 494.60 by removing paragraph (d) and redesignating paragraph (e) as paragraph (d).

■ 40. Add § 494.62 to subpart B to read as follows:

§ 494.62 Condition of participation: Emergency preparedness.

The dialysis facility must comply with all applicable Federal, State, and local emergency preparedness requirements. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. The dialysis facility must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The dialysis facility must develop and maintain an emergency preparedness plan that must be evaluated and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, the type of services the dialysis facility has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the dialysis facility's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts. The dialysis facility must contact the local emergency preparedness agency at least annually to confirm that the agency is aware of the dialysis facility's needs in the event of an emergency.

(b) *Policies and procedures.* The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. At a minimum, the policies and procedures must address the following:

(1) A system to track the location of on-duty staff and sheltered patients in the dialysis facility's care during and after an emergency. If on-duty staff and

sheltered patients are relocated during the emergency, the dialysis facility must document the specific name and location of the receiving facility or other location.

(2) Safe evacuation from the dialysis facility, which includes staff responsibilities, and needs of the patients.

(3) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(4) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

(5) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(6) The development of arrangements with other dialysis facilities or other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to dialysis facility patients.

(7) The role of the dialysis facility under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(8) How emergency medical system assistance can be obtained when needed.

(9) A process by which the staff can confirm that emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, are on the premises at all times and immediately available.

(c) *Communication plan.* The dialysis facility must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other dialysis facilities.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional or local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) Dialysis facility's staff.

(ii) Federal, State, tribal, regional, or local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the dialysis facility's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the dialysis facility's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) *Training, testing, and orientation.* The dialysis facility must develop and maintain an emergency preparedness training, testing and patient orientation program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training, testing, and patient orientation program must be evaluated and updated at least annually.

(1) *Training program.* The dialysis facility must do all of the following:

(i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually. Staff training must:

(iii) Demonstrate staff knowledge of emergency procedures, including informing patients of—

(A) What to do;

(B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;

(C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and

(D) How to disconnect themselves from the dialysis machine if an emergency occurs.

(iv) Demonstrate that, at a minimum, its patient care staff maintains current CPR certification; and

(v) Properly train its nursing staff in the use of emergency equipment and emergency drugs.

(vi) Maintain documentation of the training.

(2) *Testing.* The dialysis facility must conduct exercises to test the emergency plan at least annually. The dialysis facility must do all of the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the dialysis facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ESRD is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the dialysis facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the dialysis facility's emergency plan, as needed.

(3) *Patient orientation: Emergency preparedness patient training.* The facility must provide appropriate orientation and training to patients, including the areas specified in paragraph (d)(1) of this section.

(e) *Integrated healthcare systems.* If a dialysis facility is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the dialysis facility may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following:

(i) A documented community–based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

Dated: March 9, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: April 6, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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Part III

The President

Presidential Determination No. 2016–11 of September 13, 2016—Continuation of the Exercise of Certain Authorities Under the Trading With the Enemy Act

Federal Register
Vol. 81, No. 180
Friday, September 16, 2016

Presidential Documents

Title 3—

The President

Presidential Determination No. 2016–11 of September 13, 2016

Continuation of the Exercise of Certain Authorities Under the Trading With the Enemy Act

Memorandum for the Secretary of State [and] the Secretary of the Treasury

Under section 101(b) of Public Law 95–223 (91 Stat. 1625; 50 U.S.C. 4305 note), and a previous determination on September 11, 2015 (80 *FR* 55503, September 16, 2015), the exercise of certain authorities under the Trading With the Enemy Act is scheduled to terminate on September 14, 2016.

I hereby determine that the continuation for 1 year of the exercise of those authorities with respect to Cuba is in the national interest of the United States.

Therefore, consistent with the authority vested in me by section 101(b) of Public Law 95–223, I continue for 1 year, until September 14, 2017, the exercise of those authorities with respect to Cuba, as implemented by the Cuban Assets Control Regulations, 31 C.F.R. Part 515.

The Secretary of the Treasury is authorized and directed to publish this determination in the *Federal Register*.

THE WHITE HOUSE,
Washington, September 13, 2016

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